INSTITUTIONAL ETHICS COMMITTEE

SURENDERA DENTAL COLLEGE & RESEARCH INSTITUTE

HH GARDENS, KARNI ROAD

SRI GANGANAGAR, INDIA

IEC-SDCRI GENERAL INFORMATION

This document

for

Institutional Ethics Committee

of

SURENDERA DENTAL COLLEGE & RESEARCH INSTITUTE

is

Prepared by

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Department of Orthodontics & Dentofacial Orthopedics

According to and adapted from

Indian Council of Medical Research guidelines

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SOP INDEX

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Terms of reference of Institutional Ethical Committee-SDCRI

1. Responsibilities of the IEC-SDCRI

1. To protect and safeguard the dignity, rights, safety and well being of all actual or potential research participants.

2. To consider the principle of justice, that the benefits and burdens of research be distributed fairly among all groups and classes in society taking into account age, gender, economic status, culture and ethic consideration.

3. To provide advice to the researchers on all aspects of the welfare and safety of research participants after ensuring the scientific soundness of the proposed research.

2. Appointment of members of IEC-SDCRI

The Managing Director, SDCRI, will appoint the committee members and act as an appellate authority to appoint the committee or to handle disputes.

The IEC will consist of 8-12 members and a minimum of 5 members will form the quorum for taking a decision regarding any submitted research.

The EC will also examine the scientific issues and function as Scientific Committee.

3. Term of the IEC-SDCRI

The term of EC membership will be 3 years.

One month before the dissolution of the EC, new EC members will be appointed for smooth takeover of the EC office.

The new EC members can take part in the meetings, however, they will not have the voting rights till the term of the new committee begins.

4.Conditions of appointment

Chairperson, Member Secretary, Members, Alternate Chairperson, Alternate Members and Independent Consultants are appointed to the IEC under the following conditions:

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- Willingness to abide by the requirements laid in the SOP
- Willingness to publicize his/her full name, profession, and affiliation
- All financial accountability, reimbursement for work and expenses, if any, within or related to the IEC should be recorded and made available to the public upon request
- All IEC-SDCRI Members and Independent Consultants must sign Confidentiality / Conflict of Interest Agreements regarding meeting deliberations, applications, information on research participants and related matters

5.General requirements for Every EC member

1. Provide a recent signed CV and training certificates on human research protection and good clinical practice (GCP) guidelines, if applicable;

2. Either be trained in human research protection and/or GCP at the time of induction into the EC, or must undergo training and submit training certificates within 6 months of appointment (or as per institutional policy);

3. Be willing to undergo training or update their skills/knowledge during their tenure as an EC member;

4. Be aware of relevant guidelines and regulations;

5. Bead, understand, accept and follow the COI policy of the EC and declare it, if applicable, at the appropriate time;

6. Sign a confidentiality and conflict of interest agreement/s;

7. Be willing to place her/his full name, profession and affiliation to the EC in the public domain; and

8. Be committed and understanding to the need for research and for imparting protection to research participants in research.

6. Composition of IEC-SDCRI

1. **Chairperson** – Non-affiliated. A person with academic background of at least 8 years with previous experience of research.
2. **Member secretary** – Affiliated. Should be a staff member of the institution
   - Should have knowledge and experience in clinical research and ethics, be

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motivated and have good communication skills
• Should be able to devote adequate time to this activity which should be
protected by the institution.

3. **One** – two persons from basic medical science area (Basic medical scientists) – Affiliated/non-affiliated. Non-medical or medical person with qualifications in basic medical sciences. In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a **pharmacologist**
4. **One- two clinicians** - Affiliated/non-affiliated. Should be individual/s with recognized medical/dental qualification, expertise and training
5. **One legal expert or retired judge**- Affiliated/non-affiliated.
   - Should have a basic degree in Law from a recognized university, with experience
   - Desirable: Training in medical law
6. **One social scientist / representative of non governmental agency** - Affiliated/non-affiliated. Should be an individual with social/behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities
7. **One lay person** from the community - Non-affiliated

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7. Responsibilities of IEC-SDCRI members

S. NO	MEMBERS OF EC	QUALIFICATIONS	RESPONSIBILITIES
1.	**Chairperson**	Non-affiliated A well-respected person from any background with prior experience of having served/ serving in an EC	• Conduct EC meetings and be accountable for independent and efficient functioning of the committee • Ensure active participation of all members (particularly non-affiliated, non-medical/ non-technical) in all discussions and deliberations • Ratify minutes of the previous meetings • In case ofanticipated absence ofboth Chairperson and Vice Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting. • Seek COI declaration from members and ensure quorum and fair decision making. • Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc
2.	**Member Secretary**	Affiliated • Should be a staff member of the institution • Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills Should be able to devote adequate time to this activity	Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review • Schedule EC meetings, prepare the agenda and minutes • Organize EC documentation, communication and archiving • Ensure training of EC secretariat and EC members • Ensure SOPs are updated as and when required • Ensure adherence of EC functioning to the SOPs

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		which should be protected by the institution	• Prepare for and respond to audits and inspections • Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review. • Assess the need for expedited review/ exemption from review or full review. Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives. • Ensure quorum during the meeting and record discussions and decisions
3.	**Basic Medical Scientist(s)**	Affiliated/ non-affiliated Qualifications - • Non-medical or medical person with qualifications in basic medical sciences • In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist	•Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report • For clinical trials, pharmacologist to review the drug safety and pharmacodynamics
4.	**Clinician(s)**	Affiliated/ non-affiliated Qualifications - • Should be individual/s with recognized medical qualification, expertise and training	• Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics • Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report) • Review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation. • Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
5.	**Legal expert/s**	Affiliated/ non-affiliated Qualifications - • Should have a basic degree in Law from a recognized	• Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance

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		university, with experience • Desirable: Training in medical law	document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc. • Interpret and inform EC members about new regulations if any
6.	**Social scientist/ philosopher/ ethicist/theologian**	Affiliated/ non-affiliated Qualifications - • Should be an individual with social/ behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities	•Ethical review of the proposal, ICD along with the translations. • Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any • Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.
7.	**Lay person(s)**	Non-affiliated Qualifications - • Literate person from the public or community • Has not pursued a medical science/ healthrelated career in the last 5 years • May be a representative of the community from which the participants are to be drawn • Is aware of the local language, cultural and moral values of the community • Desirable: involved in social and community welfare activities	• Ethical review of the proposal, ICD along with translation(s). • Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. • Serve as a patient/participant/ community representative and bring in ethical and societal concerns. • Assess on societal aspects if any.

- The Chairperson and Member Secretary could have dual roles in the ethics committee. They could fulfil a role based on their qualifications (such as that of clinician, legal expert, basic scientist, social scientist, lay person etc.) in addition to taking on the role of Chairperson or Member Secretary.

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8. Selection of independent consultants:

The IEC-SDCRI may invite subject experts as independent consultants who may be consulted if required. They may also be invited to attend IEC meetings to give expert opinion on a specific proposal but they will not have the voting rights.

9. Training of IEC-SDCRI members:

- Upon appointment as a member IEC-SDCRI, the new member will have to read the entire guideline manual of IEC-SDCRI within one month of his/her appointment.
- Upon constitution of new committee at the end of 3 year term, a one day workshop will be held for the benefit of the members by the outgoing team/ Chairman/member secretary of new team or by invited faculty. This will be in addition to mandatory reading of the entire IEC-SDCRI guidelines and filling of self-assessment form.
- All the members will also be expected to make themselves acquainted with the most recent ICMR guidelines
- All the members will also be motivated to attend workshops and training related to research and ethics. Upon completion of such courses/ training the members have to submit a copy of training certificate to the IEC-SDCRI office.
- In case of any changes in the guidelines, the changes will be communicated via notices/ meetings to all the members of IEC-SDCRI.

10. Procedure for allowing guest or observer in IEC-SDCRI meetings

- At least 2 meetings in every academic year should be held with an external observer. The external observer will be appointed by Chairman/ Member secretary.
- The external observer will submit his/her obervations/suggestions to the Chairman / Member Secretary.
- The observer will not have voting rights.
- External guests wanting to attend IEC-SDCRI meeting deliberations may do after taking written permission from Chairman/ member secretary.
- The guest will not have right to take part in the decision making process of the IEC-SDCRI .
- The guest will not have voting right.

11. Consent by members of IEC-SDCRI

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After appointment as member of IEC-SDCRI, the members have to submit the consent letter in the following format to the IEC-SDCRI office.

Consent letter for members of IEC:

To

The Director

Surendera Dental College and Research Institute

HH Gardens

Karni Road

Sri Ganganagar

Rajasthan- 335001

Sub: Consent to be a member of IEC, SDCR&I

Sir,

I accept the invitation to become a member of IEC of Surendera Dental College and Research Institute. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues. I shall be willing to publicize my full name, profession and affiliation. I shall make available to the public on request, all reimbursement for work and expenses if any related to IEC. I shall not keep any literature or study related document with me after the discussion and final review. I shall maintain all the research project related information confidential and shall not reveal the same to anyone other than project related personnel. I herewith enclose my CV.

Thanking You,

Yours sincerely,

Signature ----------

Name of Member.----------

Date Address and Telephone No:

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12. Resignation, Disqualification, Replacement of Members Chairperson

The letter of resignation should be addressed to Director and must be submitted to the Chairperson. Ethics committee then recommends it to the Director.

Members may also be disqualified from continuance in the following circumstances:

- Absence for three consecutive meetings. (Both physical presence or technical review)
- Should the Chairperson provide written arguments to the (other) members and there is 2/3rd majority.
- Member does not comply to the responsibilities set for the members (stubborn- sets up stage for argument/ non-punctual/ not thorough with the job assigned)
- In case of Legal or Conflict of interest or mis-conduct.

Members that have resigned or have been disqualified may be replaced by Director/ Officer-in-Charge.

13. The review process:

The EC secretariat will screen proposals for completeness before categorizing as: *exempted from review, expedited review or full committee review.* All research proposals must be submitted to the EC. The decision on the type of review required rests with the EC and will be decided on a case-to-case basis. Researchers can approach the EC with appropriate justification for the proposal to be considered as exempt, expedited or if waiver of consent is requested

13.1 Categorization of submitted protocols for ethical review:

Exemption from review

Proposals which present less than minimal risk fall under this category as may be be seen in following situations :

i. Research on educational practices such as instructional strategies or effectiveness of or the

comparison among instructional techniques, curricula, or classroom management methods.

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Exceptions:

1. When research on use of educational tests, survey or interview procedures, or observation of public behavior can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.
2. When interviews involve direct approach or access to private papers.

Expedited Review

The proposals presenting no more than minimal risk to research participants may be subjected to expedited review. The Member- Secretary and the Chairperson of the IEC or designated member of the Committee or Subcommittee of the IEC may do expedited review only if the protocols involve -

1. Minor deviations from originally approved research during the period of approval (usually of one year duration).

2. Revised proposal previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.

3. Research activities that involve only procedures listed in one or more of the following

categories :

a. Clinical studies of drugs and medical devices only when -

i. Research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population

or

ii. Adverse Event (AE) or unexpected Advcerse Drug Reaction (ADR) of minor nature is reported.

4. Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.

5. When in emergency situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and the same participants should not be includedin the clinical trial that may be initiated later based on the findings of the pilot study.

a. **Research on interventions in emergency situation**. When proven prophylactic, diagnostic, and therapeutic methods do not exist or have been ineffective, physicians may use new intervention as investigational drug (IND) / devices/ vaccine to provide

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emergency medical care to their patients in life threatening conditions. Research in such instance of medical care could be allowed in patients -

i. When consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible. However, information about the intervention should be given to the relative/ legal guardian when available later;
ii. When the intervention has undergone testing for safety prior to its use in emergency situations and sponsor has obtained prior approval of dcgi;
iii. Only if the local iec reviews the protocol since institutional responsibility is of paramount importance in such instances.
iv. If data safety monitoring board (dsmb) is constituted to review the data;

b. Research on disaster management

A disaster is the sudden occurrence of a calamitous event at any time resulting in substantial material damage, affecting persons, society, community or state(s). It may be periodic, caused by both nature and humans and creates an imbalance between the capacity and resources of the society and the needs of the survivors or the people whose lives are threatened, over a given period of time. It may also be unethical sometimes not to do research in such circumstances. Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities, and therefore, the following points need to be considered when reviewing such research:

i. Research planned tobe conducted after a disaster should be essential culturally sensitive and specific in nature with possible application in future disaster situations.

ii. Disaster-affected community participation before and during the research is essential and its representative or advocate must be identified.

iii. Extra care must be taken to protect the privacy and confidentiality of participants and communities.

iv. Protection must be ensured so that only minimal additional risk is imposed.

v. The research undertaken should provide direct or indirect benefits to the participants, the disaster-affected community or future disaster- affected population and *a priori* agreement should be reached on this, whenever possible, between the community and the researcher.

vi. All international collaborative research in the disaster-affected area should be done with a local partner on equal partnership basis.

vii. Transfer of biological material, if any, should be as per Government rules taking care of intellectual property rights issues.

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Full Review

All research presenting with more than minimal risk, proposals/ protocols which do not qualify for exempted or expedited review and projects that involve vulnerable population and special groups shall be subjected to full review by all the members.

While reviewing the proposals, the following situations may be carefully assessed against the existing facilities at the research site for risk/benefit analysis:

a. Collection of blood samples by finger prick, heel prick, ear prick, or venipuncture:

1. From healthy adults and non-pregnant women who weigh normal for their age and not more than 500 ml blood is drawn in an 8 week period and frequency of collection is not more than 2 times per week;
2. From other adults and children, where the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected has been considered and not more than 50 ml or 3 ml per kg, whichever is lesser is drawn in an 8 week period and not more than 2 times per week;
3. From neonates depending on the haemodynamics, body weight of the baby and other purposes not more than 10% of blood is drawn within 48 – 72 hours. If more than this amount is to be drawn it becomes a risky condition requiring infusion/blood transfusion;
4. Prospective collection of biological specimens for research purposes by noninvasive means. For instance:
    1. Skin appendages like hair and nail clippings in a non-disfiguring manner;
    2. Dental procedures - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction of permanent teeth; supra and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth;
    3. Excreta and external secretions (including sweat);
    4. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum or by applying a dilute citric solution to the tongue;
    5. Placenta removed at delivery;
    6. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
    7. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
    8. Sputum collected after saline mist nebulization and bronchial lavages.

b. Collection of data through noninvasive procedures routinely employed in clinical practice.

Where medical devices are employed, they must be cleared/ approved for marketing, for instance:

1. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy;

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2. Weighing or testing sensory acuity;
3. Magnetic resonance imaging;
4. Electrocardiography, echocardiography; electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow,
5. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

c. Research involving clinical materials(data, documents, records, or specimens) that will be

collected solely for non-research (clinical) purposes.

d. Collection of data from voice, video, digital, or image recordings made for research purposes.

e.Research on individual or group characteristics or behaviornot limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

13.2 Review of the submitted proposal:

The member secretary or in his/her absence, the designated member of the EC will assign a reviewer.

The review will be done by primary reviewer and the protocol of the project with informed consent and patient information sheet, advertisements or brochures, if any, will be circulated toall the other members.
The ethical review will be done in formal meetings.

EC members will be given a maximum of 3 weeks time for completion of review.

The committee will meet at regular intervals and will not keep a decision pending for more than 3 months.

The review will be based on the following ethical issues:

1.	Social values	• The basic requirement for health research to be ethically permissible is that it must have anticipated social value. The outcome of the research should be relevant to the health problems of society. All stakeholders, including sponsors, researchers and ECs must ensure that the planned research has social value.

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2.	Scientific design and conduct of the study	• Valid scientific methods are essential to make the research ethically viable as poor science can expose research participants or communities to risks without any possibility of benefit. • Although ECs may obtain documentation from a prior scientific review, they will also determine that the research methods are scientifically sound, and will examine the ethical implications of the chosen research design or strategy. • The EC can raise scientific concerns (even if the study has prior approval of a scientific committee) if it may affect quality of research and or safety of research participants.
3.	Benefit risk assessment	• The benefits accruing from the planned research either to the participants or to the community or society in general must justify the risks inherent in the research. • Risks may be physical, psychological, economic, social or legal and harm may occur either at an individual level or at the family, community or societal level. It is necessary to first look at the intervention under investigation and assess its potential harm and benefits and then consider the aggregate of harm and benefits of the study as a whole. • The EC will review plans for risk management, including withdrawal criteria with rescue medication or procedures. • The EC will give advice regarding minimization of risk/ discomfort wherever applicable.
4.	Selection of the study population and recruitment of research participants	• Recruitment should be voluntary and non-coercive. Participants should be fairly selected as per inclusion and exclusion criteria. However, selection of participants should be distributive such that a particular population or tribe or economic group is not coerced to participate or benefit. • Participants should be able to opt out at any time without their routine care being affected. • No individual or group of persons must bear the burden of participation in research without accruing any direct or indirect benefits. • Vulnerable groups may be recruited after proper justification is provided.
5.	Payment for participation	• Plans for payment for participation, reimbursement of incurred costs, such as travel or lost wages, incidental expenses and other inconveniences will be reviewed. • There is a need to determine that payments are not so large as to encourage prospective participants to participate in the research without

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		due consideration of the risks or against their better judgement. No undue inducement must be offered.
6.	Protection of research participants privacy and confidentiality	• ECs will examine the processes that are put in place to safeguard participants' privacy and confidentiality • Research records to be filed separately than routine clinical records such as in a hospital setting
7.	Community considerations	• The EC will ensure that due respect is given to the community, their interests are protected and the research addresses the community's needs. • The proposed research should not lead to any stigma or discrimination. Harm, if any, should be minimized. • Plans for communication of results to the community at the end of the study will be carefully reviewed. • It is important to examine how the benefits of the research will be disseminated to the community
8.	Qualifications of researchers and adequacy of assessment of study sites	• The EC will look at the suitability of qualifications and experience of the PI to conduct the proposed research along with adequacy of site facilities for participants
9.	Disclosure or declaration of potential COI	• The EC will review any declaration of COI by a researcher and suggest ways to manage these. • The EC will manage COI within the EC and members with COI will leave the room at the time of decision making in a particular study
10.	Plans for medical management and compensation for study related injury	• The proposed plan for tackling any medical injuries or emergencies should be reviewed. • Source and means for compensation for study related injury should be ascertained
11.	Review of the informed consent process	• the process used for obtaining informed consent, including the identification of those responsible for obtaining consent and the procedures adopted for vulnerable populations; • the adequacy, completeness and understandability of the information to be given to the research participants, and when appropriate, their LARs

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14. Meeting requirements

* All the IEC meetings will be held regularly on scheduled dates that are announced and notified in advance.

* Additional review meetings can also be held with short notice as and when required.

* Meetings will be planned in accordance with the need of the work load.

* Member will be given 10 days time in advance to review study proposals and the relevant documents.

* Minutes of the IEC meetings, all the proceedings and deliberation will be documented.

* Signatures of all the members who have participated in the meeting will be obtained on the minutes of the meeting document.

* Applicant, sponsor or investigator may be invited to present the proposal or elaborate on specific issues.

* Independent expert may be invited to the meeting or to provide written comment, subject to applicable confidentiality agreement.

15. Quorum requirements

1. A minimum of five members should be present in the meeting room.
2. The quorum should include both medical, non- medical or technical or/and non-technical members.(*Medical members are clinicians with appropriate medical qualifications. Technical members are persons with qualifications related to a particular branch in which the study is conducted, for example social sciences)*
3. Minimum one non-affiliated member should be part of the quorum.
4. Preferably the lay person should be part of the quorum.
5. The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCOrequirements and will be changed as soon as new guidelines from CDSCO are released.
6. No decision is valid without fulfilment of the quorum.

16. Agenda Preparation, meeting procedures and minutes of the meeting

The agenda of the upcoming IEC meeting will be prepred by the IEC office and circulated among the members by e-mail.

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The IEC will meet periodically for reviewing new proposals, evaluate annual progress of ongoing ones, review serious adverse event (SAE) reports and assess final reports of all research activities involving human beings through a previously scheduled agenda, amended wherever appropriate. The following points will be considered while doing so :

1. The decision will be taken by a broad consensus after the quorum requirements are fulfilled to recommend / reject / suggest modification for a repeat review or advice appropriate steps. The Member Secretary will communicate the decision in writing to the PI.
2. If a member has conflict-of-interest (COI) involving a project then s/he should submit this in writing to the chairperson before the review meeting, and it will also be recorded in the minutes.,
3. If one of the members has her/his own proposal for review or has any COI then s/he will withdraw from the IEC while the project is being discussed
4. A negative decision will always be supported by clearly defined reason
5. The IEC may decide to reverse its positive decision on a study if it receives information that may adversely affect the risk/ benefit ratio.
6. The discontinuation of a trial will be ordered if the IEC finds that the goals of the trial have already been achieved midway or unequivocal results are obtained.
7. In case of premature termination of study, notification will include the reasons for termination along with the summary of results conducted till date.
8. The following circumstances require the matter to be brought to the attention of IEC:
   a. any amendment to the protocol from the originally approved protocol with proper justification;
   b. serious and unexpected adverse events and remedial steps taken to tackle them;
   c. any new information that may influence the conduct of the study.
9. If necessary, the applicant/investigator will be invited to present the protocol or offer clarifications in the meeting. Representative of the patient groups or interest groups can be invited during deliberations to offer their viewpoint.
10. Subject experts may be invited to offer their views, but will not take part in the decision making process. However, her / his opinion will be recorded.

17. Procedure for allowing guest or observer in IEC-SDCRI meetings

1. At least 2 meetings in every academic year should be held with an external observer. The external observer will be appointed by Chairman/ Member secretary.
2. The external observer will submit his/her obervations/suggestions to the Chairman / Member Secretary.
3. The observer will not have voting rights.
4. External guests wanting to attend IEC-SDCRI meeting deliberations may do after taking written permission from Chairman/ member secretary.
5. The guest will not have right to take part in the decision making process of the IEC-SDCRI .
6. The guest will not have voting right.

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18. Types of decisions:

The IEC-SDCRI will give one of the following decisions:
•**Approved** – with or without suggestions or comments;
•**Revision with minor modifications/amendments** – approval is given after examination by the Member Secretary or expedited review, as the case may be;
•**Revision with major modifications for resubmission** – this will be placed before the full committee for reconsideration for approval; or
•**Not approved (or termination/revoking of permission if applicable**) – clearly defined reasons must be given for not approving/terminating/revoking of permission

19. Review of Resubmitted protocols and amended protocols

• **Revision with minor modifications/amendments** – approval is given after examination by the Member Secretary or expedited review, as the case may be;
• **Revision with major modifications for resubmission** – this will be placed before the full committee for reconsideration for approval

20. Continuing review of protocols

Approval may be granted for the entire duration of the proposed research or can be subject to annual review depending on the type of study. The EC will review the annual report (counted from the day of approval or date of actual start of the study) for continuation. Depending on the risk involved, the progress of the proposal may be monitored annually or at shorter intervals (quarterly, half yearly) as per EC decision. Approval may be continued if progress is satisfactory.
EC may decide to reverse its positive decision on a study if it receives information that may adversely affect the benefit-risk assessment.

21. Review of SAE (Special Adverse Events) reports

Any SAE report will be investigated by the IEC-SDCRI

The IEC will investigate for the compliance of SAE regulations by the researcher.

The IEC will investigate for deviation from the protocol

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The IEC will examine the measures taken for medical management of SAE. The participants will not bear the costs for the management of study-related-injury whether they are in the intervention arm or the control arm.

The IEC will monitor the compensation given for research-related injuries (if applicable) as per regulatory requirement.

For protocol deviations/violations the EC will examine the corrective actions taken. In case of serious violations EC will have the power to halt the study and report to the institutional head/ government authorities where there is non-compliance to ethical standards.

Reports of monitoring done by the sponsor may also be sought by the EC

22. Site monitoring

Depending on the risk level assessed by the IEC for a protocol, research site monitoring of the protocol will be done.

1. **Routine monitoring**: it will be decided by the IEC at the time of initial review or during continuing review if routine monitoring is required. The reason may be involvement of higher risk or vulnerable participants or if there is any other reason for concern.
2. '**For cause' monitoring** :
   high number of protocol violations/ deviations
   - large number of proposals carried out at the study site or by the same researcher
   - large number of SAE reports
   - high recruitment rate
   - complaints received from participants
   - any adverse media report
   - adverse information received from any other source
   - non-compliance with EC directions
   - misconduct by the researcher
   - any other cause as decided by the EC.

23. Emergency meetings of IEC-SDCRI

An emergency meeting of the IEC-SDCRI can be called upon by the Chairman or member secretary

At least a notice of 24 hrs must be given for the emergency meeting.

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A request for emergency meeting may also be submitted in writing by any of the members of the IEC to the member secretary. However, the decision to hold the emergency meeting will be taken by the chairman or member secretary IEC-SDCRI

Following may qualify as some of the reasons, but not all, for calling an emergency meeting of IEC.

1. Adverse events
2. Significant deviation from study protocol
3. Participant complaints
4. Plagiarism
5. Issues related to special groups

24. Study completion reports

A final clinical study report must be submitted **within a year** after completion or discontinuation of **the clinical trial**, unless a longer period is specified in the protocol.

The end of a study involving persons is defined as the date of the 'last participant's final follow-up visit', unless otherwise specified in the protocol. The period of data collection should be defined in the research project protocol.

The following form should be filled and submitted to the IEC-SDCRI

The end of a clinical trial or of a research project is acknowledged by Ethics Committees. If there is no feedback within 15 days, the 'end of study notification' has been silently acknowledged by the Ethics Committee.

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Study Completion Report

This notification concerns the end of a Clinical Trial or the end of a Research Project involving persons	Yes ☐ No ☐
This notification concerns the end of further use of health-related personal data and/or biological material for research, research involving deceased persons or research involving Embryos and Fetuses from induced abortion and from spontaneous abortions including stillbirths	Yes ☐ No ☐
IEC-SDCRI registration number	
Title of the study	
Sponsor	
Applicant	
Has the study been terminated prematurely?	No ☐ Yes ☐ If yes, give the date of the early termination: [day/month/year]
If yes: **describe the reasons for the early termination** - e.g. safety reason, difficulties recruiting participants, costs exceeded available budget, etc... **What are the consequences of the early termination for the evaluation of the results of the study?** **If applicable give the overall risk benefit**	

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assessment of the investigational medicinal product (IMP).	
Date: Study start -	[day/month/year]
Date: End of study -	[day/month/year]
Is a summary of the final report on the clinical trial available and enclosed with this form?	Yes ☐ No ☐ If No, submit to the Ethics Committee within a year after completion or discontinuation of the clinical trial.

Signature of the applicant

I hereby confirm that the above information given on this declaration is correct; and

for ClinO study only, that the clinical trial summary report will be submitted to the Ethics Committee within a year after completion or discontinuation of the clinical trial, unless a longer period is specified in the protocol.

Date and place:

Print name:

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25. Management of premature termination, suspension, discontinuation of the study

Ethics Committee must be notified within **15 days** of a discontinuation or an early termination of a **clinical trial**

Ethics Committee must be notified within **90 days** of the discontinuation or the early termination of a **research project**

The information must be conveyed to the IEC-SDCRI in the following form.

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& RESEARCH INSTITUTE
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INSTITUTIONAL ETHICS COMMITTEE
SURENDERA DENTAL COLLEGE & RESEARCH INSTITUTE
HH GARDENS, SRI GANGANAGAR, INDIA

PrematureTermination of Study Report

IEC-SDCRI registration number	
Title of the study	
Sponsor	
Applicant	
Has the study been terminated prematurely?	No ☐ Yes ☐ If yes, give the date of the early termination: [day/month/year]
If yes: **describe the reasons for the early termination** - e.g. safety reason, difficulties recruiting participants, costs exceeded available budget, etc... **What are the consequences of the early termination for the evaluation of the results of the study?** **If applicable give the overall risk benefit assessment of the investigational medicinal product (IMP).**	
Date: Study start -	[day/month/year]
Date: End of study -	[day/month/year]
Is a summary of the final report on the clinical trial available and enclosed with this form?	Yes ☐ No ☐ If No, submit to the Ethics Committee within a year after completion or discontinuation of the clinical trial.

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Signature of the applicant

I hereby confirm that the above information given on this declaration is correct; and

for ClinO study only, that the clinical trial summary report will be submitted to the Ethics Committee within a year after completion or discontinuation of the clinical trial, unless a longer period is specified in the protocol.

Date and place:

Print name:

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26. Review of Final Reports

The final report has to be filed with the IEC-SDCRI within a period of one year in the following format

1. Title of the study
2. Principal investigators
3. Copy of IEC clearance letter
4. Introduction
5. Aims and Objectives
6. Materials and methods
7. Adverse events
8. Protocol deviations
9. Patient-wise demographic variables
10. Patient-wise other outcome variables recorded
11. Summary of results
12. Statistical methods employed
13. Tables, figures, graphs
14. Conclusion
15. List of patients who discontinued the study

27. Documentation and Achieving

All documentation and communication of an IEC are to be dated, filed and preserved for 3 years. Strict confidentiality is to be maintained during access and retrieval procedures. The following records will be maintained:

a. The Constitution and composition of the IEC;
b. Signed and dated copies of the latest the curriculum vitae of all IEC members with records of training if any;
c. Standing operating procedures of the IEC;
d. National and International guidelines;
e. Copies of protocols submitted for review;
f. All correspondence with IEC members and investigators regarding application, decision and follow up;
g. Agenda of all IEC meetings;
h. Minutes of all IEC meetings with signature of the Chairperson;
i. Copies of decisions communicated to the applicants;
j. Record of all notification issued for premature termination of a study with a summary of the reasons;
k. Final report of the study including microfilms, cds and Video recordings.

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28. Maintenance of active study files

All the study files where the research is still continuing or where study completion report is not filed will be treated as active study files and will be separately kept in the IEC.

All the active study files will be reviewed at least once a year till filing of the study completion report.

29. Retrieval of documents

The documents access will be restricted to Chairman IEC and Secretary IEC.

Under no circumstances the documents will be accessed by non-IEC personal to maintain confidentiality of the research.

The document may be retrieved and shown to principal investigator on written request and approval.

The approving authority for retrieval of document for principal investigator will be the chairman IEC or Secretary IEC.

30. Maintaining confidentiality of ECs documents

All the documents will be maintained by the IEC office in complete confidentiality.

The access to the documents will be restricted to secretary IEC and Chairman IEC.

Under no circumstances the research design or research material be let out in public domain without the consent of the principal investigator.

Access to document with/ without permission by principal investigator to any document which is not related to his/her own study is strictly prohibited.

Principal investigator may access his/her own study document on written permission by chairman or member secretary.

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31. Records of communication

1. Meetings will be minuted, approved and signed by the Chairperson/ alternate Chairperson/ designated member of the committee.

2. all the communications with the principal investigators and with members of IEC will be documented and archieved for 3 years from the completion of the study.

32. Review and inspection of IEC

The IEC will be reviewed every 3 years. This review will consist of the following:

1. Status of all active study files
2. Review of the composition of the IE committee
3. Review of all the adverse events reported in previous 3 years and the action taken thereof
4. Review of all the study participants comoplaints during previous 3 years and the action taken thereof
5. Review of all the complaints by principal investigators and the action taken thereof
6. Review of the budgetary provision for IEC
7. Financial audit of the IEC.

33. Review of new medical device studies

The review of new medical device studies will be done according to the ethical guidelines Indian GSP as well as applicable regulations for medical and medicaed devices, that is, GSR 78 E dated 31.1.2017 or as per amendments/ modifications issued from time-to-time.

The protocol will be evaluated for the presence of safety data of the medical device in animals and the likely risks posed by the device (according to Drugs and Cosmetic Rules, 1945)

The procedures to introduce the medical device in the patients will also be evaluated for safety.

The cost to be incurred by the patient will be avaluated (whether it will be borne by the researcher or the patient and if by the patient, then at what cost to the patient)

A timeline will be decided by the IEC for reporting of SAE according to the type of medical device.

In case of implantable medical device, the consent form will be examined for the course of action in case the participant wants to withdraw from a trial.

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The obligations of the sponsor with regard to post-trial period will be examined

The duration of follow-up will be examined for its adequacy to detect late onset adverse reactions.

For Biologicals and Biosimilars a subject expert may be called for reviewing the protocol.

For Biologicals and Biosimilars the presence of data regarding manufacturing, characterization, preclinical data and bioassay in the protocol will be assessed.

Stem cell research will be examined for adherence to ICMR and DBT published Guidelines for Stem Cell Research and Therapy in 2007, 2013 and revised as National Guidelines for Stem Cell Research in 2017.

34. Condition for granting waiver of consent

The EC may grant consent waiver in the following situations:
Research cannot practically be carried out without the waiver and the waiver is scientifically justified;
Retrospective studies, where the participants are de-identified or cannot be contacted;
Research on anonymized biological samples/data;
Certain types of public health studies/surveillance programmes/programme evaluation
studies;
Research on data available in the public domain; or
Research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent. Attempt should be made to obtain the participant's consent at the earliest.

Electronic/online consent may be obtained for research involving sensitive topics while
safeguarding information and data and also if required for regulatory clinical trials

35. Confidentiality agreement

A statement must be included as part of PART – I of the consent (Information sheet) document explaining how the confidentiality will be maintained.

The following general guidelines (adapted from ICMR Guidelines -2017) will be the guiding principles for the confidentiality agreement.

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Confidentiality is the obligation of the researcher/research team/organization to the participant to safeguard the entrusted information. It includes the obligation to protect information from unauthorized access, use, disclosure, modification, loss or theft.The researcher should safeguard the confidentiality of research related data of participants and the community.

Potential limitations to ensure strict confidentiality must be explained to the participant. Researchers must inform prospective participants that although every effort will be made to protect privacy and ensure confidentiality, it may not be possible to do so under certain circumstances.

Any publication arising out of research should uphold the privacy of the individuals by ensuring that photographs or other information that may reveal the individual's identity are not published. A specific re-consent would be required for publication, if this was not previously obtained.

Some information may be sensitive and should be protected to avoid stigmatization and/or discrimination (for example, HIV status; sexual orientation such as lesbian, gay, bisexual, and transgender (LGBT); genetic information; or any other sensitive information)

While conducting research with stored biological samples or medical records/data, coding or anonymization of personal information is important and access to both samples and records should be limited. See section 11 for further details.

Data of individual participants/community may be disclosed in certain circumstances with the permission of the EC such as specific orders of a court of law, threat to a person's or community's life, public health risk that would supersede personal rights to privacy, serious adverse events (SAEs) that are required to be communicated to an appropriate regulatory authority etc.

36. Payment to the participant for participating in the research

If applicable, participants may be reimbursed for expenses incurred relating to their participation in research, such as travel related expenses. Participants may also be paid for inconvenience incurred, time spent and other incidental expenses in either cash or kind or both as deemed necessary (for example, loss of wages and food supplies).

Participants should not be made to pay for any expenses incurred beyond routine clinical care and which are research related including investigations, patient work up, any interventions or associated treatment. This is applicable to all participants, including those in comparator/control groups.

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If there are provisions, participants may also receive additional medical services at no cost.

When the Legal Guardian is giving consent on behalf of a participant, payment should not become an undue inducement and to be reviewed carefully by the EC. Reimbursement may be offered for travel and other incidental expenses incurred due to participation of the child/ward in the research.

ECs must review and approve the payments (in cash or kind or both) and free services and the processes involved, and also determine that this does not amount to undue inducement.

37. Dealing with participants requests and complaints

The study participants will have to be provided with the Investigators contact number and IEC-SDCRI contact details.

The study participants will have to be provided with an alternative address in case the study design requires blinding. In that case the alternate contact person should be a person with detailed knowledge of the ongoing study and should be able to take decision for the benefit of the participants.

In case the participants issue is unresolved the matter will be taken up by the IEC-SDCRI and the decision taken will be binding on the principal investigators.

38. Conflict of Interest

A statement must be included as part of PART – I of the consent (Information sheet) document explaining that there is no conflict of interst.

Conflict of interest (COI) is a set of conditions where professional judgement concerning a primary interest such as participants welfare or the validity of research tends to be unduly influenced by a secondary interest, financial or non-financial (personal, academic or political). COI can be at the level of researchers, EC members, institutions or sponsors. If COI is inherent in the research, it is important to declare this at the outset and establish appropriate mechanisms to manage it.

Researchers must ensure that the documents submitted to the EC include a disclosure of interests that may affect the research.

The EC also requires that their members disclose their own COI. Upon such declaration / identification of COI by a EC member, the member will not take part in the decision making process of granting EC clearance or reviewing the protocol.

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Appropriate suggestions will be made for the management, if COI is detected at the institutional or researchers level.

EC will evaluate each study in light of any disclosed interests and ensure that appropriate means of mitigation are taken.

39. Audio-visual recording of informed consent process (adapted from

NIRRH Ethics Committee for Clinical Studies)

Principal investigator, Co-Investigator or any other medically qualified member of staff in the team, as delegated by the Principal Investigator, who have the responsibility of obtaining an informed consent, will also be responsible for ensuring AV recording of the informed consent process, storing and archiving without violating the participant confidentiality.

The PI/Co-I/medically qualified person delegated by the PI and the potential participant/LAR (and if need be the impartial witness) should sit comfortably facing each other / side-by-side in such a way that their faces will be captured in the frame simultaneously.

The PI/Co-I/medically qualified person delegated by the PI should introduce himself/herself by name, designation and his/ her role in the research, and state the current date and time.

Participant/LAR should be requested to introduce his/her name, age and address and in case of LAR, he/she should clearly state relation to actual participant as well as the reason why the participant cannot give consent. Participant/LAR should also state the language he/she understands best and is literate in. The PI/Co-I/medically qualified person delegated by the PI may facilitate this process to ensure all above points are captured in the recording.

In case participant/LAR is illiterate and an impartial witness is needed, the impartial witness should be requested to introduce himself/ herself, give his/her address and state the language that he/she is literate in.

The Participant/LAR should state that he has been informed about the fact that the entire consent process is being recorded and that he/she has agreed for the same.

The participant should be allowed to read the consent document (and this process should be recorded)

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The PI/Co-I/medically qualified person delegated by the PI should explain all the elements of the approved ICF in the language best understood by the potential participant

Explanation or narration given by the PI/Co-I/medically qualified person delegated by the PI, all the questions asked by the potential participant/LAR and answers given to them should be clearly audible and recorded.

At any point during the consent process, if the participant wishes to take more time to read/ understand the consent document, including, for example, take it home to discuss with relatives the recording shall be stopped mentioning the time of stopping. When he/she returns, the recording from the point where it was stopped before shall be resumed as mentioned before stating clearly again the date and time of recording.

The participant/LAR (wherever applicable) should be invited to sign the consent form only after satisfactory answers (in the investigator's judgement) have been given by the participant/ LAR to all the above mentioned questions.

Participant/LAR should read out all the statements mentioned in ICF as per Schedule-Y and state whether he/she agrees or not for each statement and affix signature/thumb print at the end

The actual signing process should be recorded.

The impartial witness should be requested to enter the name and details of the participant and the date the consent is documented. The impartial witness will also be requested to sign and date the consent form.

The PI/Co-I/medically qualified person delegated by the PI will also sign and date the consent form at the end of the process.

The recording will be stopped after thanking the participant.

The recording should be checked for completeness and clarity of both audio and video recording.

No editing should be done on the recording so as to maintain authenticity.

The computer/laptop should be password protected. The password will be known only to the PI and members of the study team as designated by the PI. A register should be maintained wherein, each time the data is accessed, the details of who accessed the data, date and reasons for the same this should be entered into the designated register.

The recording should be then transferred to a CD labeled according to study name, unique identifier assigned to the participant, date and time of the recording, no. of recordings (applicable during re-consenting) and archived in the external Hard drive.

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The CD should be filed in the participant binder. The original recording in the computer/laptop will be deleted when study is closed out.

40. Reviewing proposals involving vulnerable populations

Groups with an increased likelihood of incurring additional harm by becoming a research participant because of their incapability of protecting their own interests like :

1. *Legal status – children*
2. *Clinical condition – cognitive impairment, unconsciousness*
3. *Situational conditions – including but not limited to being economically or socially disadvantaged (certain ethnic or religious groups, individuals/communities which have hierarchial relationships, institutionalized persons, humanitarian emergencies, language barriers and cultural differences)*

Assessment criteria for inclusion of vulnerable populations as research participants - such participants should be included in research only when the research is directly answering the health needs or requirements of the group. On the other hand, vulnerable populations also have an equal right to be included in research so that benefits accruing from the research apply to them as well.

EC will determine vulnerability and ensure that additional safeguards and monitoring mechanisms are established. EC will also advise the researcher in this regard.

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41. GENERAL GUIDELINES

I. INFORMED CONSENT PROCESS

1. Informed Consent of Participants : For all biomedical research involving human participants, the investigator must obtain the informed consent of the prospective participant or in the case of an individual who is not capable of giving informed consent, the consent of a legal guardian. Informed consent protects the individual's freedom of choice and respect for individual's autonomy and is given voluntarily to participate in research or not. Adequate information about the research is given in a simple and easily understandable unambiguous language in a document known as the Informed Consent Form with Participant/ Patient Information Sheet. The latter should have following components as may be applicable :

1. Nature and purpose of study stating it as research
2. Duration of participation with number of participants
3. Procedures to be followed
4. Investigations, if any, to be performed
5. Foreseeable risks and discomforts adequately described and whether project involves more than minimal risk
6. Benefits to participant, community or medical profession as may be applicable
7. Policy on compensation
8. Availability of medical treatment for such injuries or risk management
9. Alternative treatments if available
10. Steps taken for ensuring confidentiality
11. No loss of benefits on withdrawal
12. Benefit sharing in the event of commercialization
13. Contact details of PI or local PI/Co-PI in multicentric studies for asking more information related to the research or in case of injury
14. Contact details of Chairman of the IEC for appeal against violation of rights
15. Voluntary participation
16. If test for genetics and HIV is to be done, counseling for consent for testing must be given as per national guidelines
17. Storage period of biological sample and related data with choice offered to participant regarding future use of sample, refusal for storage and receipt of its results

A copy of the participant/patient information sheet should be given to the participant for her/ his record. The informed consent should be brief in content highlighting that it is given of free will or voluntarily after understanding the implications of risks and benefits and s/he could withdraw without loss of routine care benefits.

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Assurance is given that confidentiality would be maintained and all the investigations/ interventions would be carried out only after consent is obtained.

When the written consent as signature or thumb impression is not possible due to sensitive nature of the project or the participant is unable to write, then verbal consent can be taken after ensuring its documentation by an unrelated witness. In some cases ombudsman, a third party, can ensure total accountability for the process of obtaining the consent. Audio-visual methods could be adopted with prior consent and adequate precaution to ensure confidentiality, but approval of EC is required for such procedures. For drug trials, if the volunteer can give only thumb impression then another thumb impression by the relative or legal custodian cannot be accepted and an unrelated witness to the project should then sign.

Fresh or re-consent is taken in following conditions :

1. Availabilty of new information which would necessitate deviation of protocol.
2. When a research participant regains consciousness from unconscious state or is mentally competent to understand the study. If such an event is expected then procedures to address it should be spelt out in the informed consent form.
3. When long term follow-up or study extension is planned later.
4. When there is change in treatment modality, procedures, site visits.
5. Before publication if there is possibility of disclosure of identity through data presentation or photographs (which should be camouflaged adequately).

Waiver of consent

Voluntary informed consent is always a requirement for every research proposal. However, this can be waived if it is justified that the research involves not more than minimal risk or when the participant and the researcher do not come into contact or when it is necessitated in emergency situations elaborated in the previous Chapter. If such studies have protections in place for both privacy and confidentiality, and do not violate the rights of the participants then IECs may waive off the requirement for informed consent in following instances:

1. When it is impractical to conduct research since confidentiality of personally identifiable information has to be maintained throughout research as may be required by the sensitivity of the research objective, *eg.*, study on disease burden of HIV/AIDS.
2. Research on publicly available information, documents, records, works, performances, reviews, quality assurance studies, archival materials or third party interviews, service programs for benefit of public having a bearing on public health programs, and consumer acceptance studies.
3. Research on anonymised biological samples from deceased individuals, left over samples after clinical investigation, cell lines or cell free derivatives like

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viral isolates, DNA or RNA from recognised institutions or qualified investigators, samples or data from repositories or registries *etc.*

4. In emergency situations when no surrogate consent can be taken.

2. Obligations of investigators regarding informed consent : The investigator has the duty to

1. Communicate to prospective participants all the information necessary for informed consent. Any restriction on participant's right to ask any questions related to the study will undermine the validity of informed consent;
2. Exclude the possibility of unjustified deception, undue influence and intimidation. Although deception is not permissible, if sometimes such information would jeopardize the validity of research it can be withheld till the completion of the project, for instance, study on abortion practices;
3. Seek consent only after the prospective participant is adequately informed. The investigator should not give any unjustifiable assurances to prospective participant, which may influence the her/his decision to participate;
4. Obtain from each prospective participant a signed form as an evidence of informed consent (written informed consent) preferably witnessed by a person not related to the trial, and in case the participant is not competent to do so, a legal guardian or other duly authorised representative;
5. Take verbal consent when the participant refuses to sign or give thumb impression or cannot do so. This can then be documented through audio or video means;
6. Take surrogate consent from the authorized relative or legal custodian or the institutional head in the case of abandoned institutionalized individuals or wards under judicial custody;
7. Renew or take fresh informed conconsent of each participant under circumstances described earlier in this chapter;
8. If participant loses consciousness or competence to consent during the research period as in alzeimer or psychiatric conditions, surrogate consent may be taken from the authorized person or legal custodian.

The investigator must assure prospective participants that their decision to participate or not will not affect the patient - clinician relationship or any other benefits to which they are entitled.

3. Essential information for prospective research participants : Before requesting an individual's consent to participate in research, the investigator must provide the individual with the following information in the language she or he is able to understand which should not only be scientifically accurate but should also be sensitive/ adaptive to their social and cultural context:

I. The aims and methods of the research;
II. The expected duration of the participation;

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III. The benefits that might reasonably be expected as an outcome of research to the participant or community or to others;
IV. Any alternative procedures or courses of treatment that might be as advantageous to the participant as the procedure or treatment to which s/he is being subjected;
V. Any foreseeable risk or discomfort to the participant resulting from participation in the study;
VI. Right to prevent use of her/ his biological sample (dna, cell-line, etc.) At any time during the conduct of the research;
VII. The extent to which confidentiality of records could be maintained ie., the limits to which the investigator would be able to safeguard confidentiality and the anticipated consequences of breach of confidentiality;
VIII. Responsibility of investigators;
IX. Free treatment for research related injury by the investigator and/ institution and sponsor(s);
X. Compensation of participants for disability or death resulting from such injury;
XI. Insurance coverage if any, for research related or other areas;
XII. Freedom of individual / family to participate and to withdraw from research any time without penalty or loss of benefits which the participant would otherwise be entitled to;
XIII. The identity of the research teams and contact persons with address and phone numbers;
XIV. Foreseeable extent of information on possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, clear mention of the same;
XV. Risk of discovery of biologically sensitive information and provision to safeguard confidentiality;
XVI. Publication, if any, including photographs and pedigree charts.

The quality of the consent of certain social and marginalized groups requires careful consideration as their agreement to volunteer may be unduly influenced by the Investigator.

2. COMPENSATION FOR PARTICIPATION

Participants may be paid for the inconvenience and time spent, and should be reimbursed for expenses incurred, in connection with their participation in research. They may also receive free medical services. When this is reasonable then it cannot be termed as benefit. During the period of research if the participant requires treatment for complaints other than the one being studied necessary **free ancillary**

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care or appropriate referrals may be provided. However, payments should not be so large or the medical services so extensive as to make prospective participants consent readily to enroll in research against their better judgment, which would then be treated as undue inducement. All payments, reimbursement and medical services to be provided to research participants should be approved by the IEC.

Care should be taken :

i. When a guardian is asked to give consent on behalf of an incompetent person, no remuneration should be offered except a refund of out of pocket expenses;
ii. When a participant is withdrawn from research for medical reasons related to the study the participant should get the benefit for full participation;
iii. When a participant withdraws for any other reasons s/he should be paid an amount proportionate to the amount of participation.

3. CONFLICT OF INTEREST

A set of conditions in which professional judgment concerning a primary interest like patient's welfare or the validity of research tends to be or appears to be unduly influenced by a secondary interest like non-financial (personal, academic or political) or financial gain is termed as Conflict of Interest (COI).

Academic institutions conducting research in alliance with industries/ commercial companies require a strong review to probe possible conflicts of interest between scientific responsibilities of researchers and business interestes. *g*(. ownership or part-ownership of a company developing a new product). In cases where the review board/ committee determines that a conflict of interest may damage the scientific integrity of a project or cause harm to research participants, the board/ committee should advise accordingly. Significant financial interest means anything of monetary value that would reasonably appear to be a significant consequence of such research including salary or other payments for services like consulting fees or honorarium per participant; equity interests in stocks, stock options or other ownership interests; and intellectual property rights from patents, copyrights and royalties from such rights. The investigators should declare such conflicts of interest in the application submitted to IEC for review. Institutions and IECs need self-regulatory processes to monitor, prevent and resolve such conflicts of interest. The IEC can determine the conditions for management of such conflicts in its SOP manual. Prospective participants in research should also be informed of the sponsorship of research, so that they can be aware of the potential for conflicts of interest and commercial aspects of the research. Those who have also to be informed of the secondary interest in financial terms should include the institution, IEC, audience when presenting papers and should be mentioned when publishing in popular media or scientific journals.

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Undue inducement through compensation for individual participants, families and populations should be prohibited. This prohibition however, does not include agreements with individuals, families, groups, communities or populations that foresee technology transfer, local training, joint ventures, provision of health care reimbursement, costs of travel and loss of wages and the possible use of a percentage of any royalties for humanitarian purposes. Undue compensation would include assistance to related person(s) for transport of body for cremation or burial, provision for insurance for unrelated conditions, free transportation to and fro for examination not included in the routine, free trip to town if the participants are from rural areas, free hot meals, freedom for prisoners, free medication which is generally not available, academic credits and disproportionate compensation to researcher / team/ institution. However, in remote and inaccessible areas some of the features mentioned above may be a necessity and culture specific. Therefore, the IEC should examine this on a case-by-case basis, as some of these elements may be justifiable for collecting vital data for national use or necessary to find if some interventions may significantly have direct impact on health policies.

4. SELECTION OF SPECIAL GROUPS AS RESEARCH PARTICIPANTS

i. ***Pregnant or nursing women*** : Pregnant or nursing women should in no circumstances be the participant of any research unless the research carries no more than minimal risk to the fetus or nursing infant and the object of the research is to obtain new knowledge about the foetus, pregnancy and lactation. As a general rule, pregnant or nursing women should not be participants of any clinical

trial except such trials as are designed to protect or advance the health of pregnant or nursing women or foetuses or nursing infants, and for which women who are not pregnant or nursing would not be suitable participants.

a. The justification of participation of these women in clinical trials would be that they should not be deprived arbitrarily of the opportunity to benefit from investigations, drugs, vaccines or other agents that promise therapeutic or preventive benefits. Example of such trials are, to test the efficacy and safety of a drug for reducing perinatal transmission of HIV infection from mother to child, trials for detecting foetal abnormalities and for conditions associated with or aggravated by pregnancy etc. Women should not be encouraged to discontinue nursing for the sake of participation in research and in case she decides to do so, harm of cessation of breast-feeding to the nursing child should be properly assessed except in those studies where breast feeding is harmful to the infant. Compensation in terms of supplying supplementary food such as milk formula should be considered in such instances.
b. Research related to termination of pregnancy : Pregnant women who desire to undergo Medical Termination of Pregnancy (MTP) could be made participants for such research as per The Medical Termination of Pregnancy Act, GOI, 1971.

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c. Research related to pre-natal diagnostic techniques : In pregnant women such research should be limited to detect the foetal abnormalities or genetic disorders as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994 and not for sex determination of the foetus.

ii. *Children* : Before undertaking trial in children the investigator must ensure that -

a. Children will not be involved in research that could be carried out equally well with adults;
b. The purpose of the research is to obtain knowledge relevant to health needs of children. For clinical evaluation of a new drug the study in children should always be carried out after the phase iii clinical trials in adults. It can be studied earlier only if the drug has a therapeutic value in a primary disease of the children;
c. A parent or legal guardian of each child has given proxy consent;
d. The assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors from the age of seven years up to the age of 18 years.;
e. Research should be conducted in settings in which the child and parent can obtain adequate medical and psychological support;
f. Interventions intended to provide direct diagnostic, therapeutic or preventive benefit for the individual child participant must be justified in relation to anticipated risks involved in the study and anticipated benefits to society;
g. The child's refusal to participate in research must always be respected unless there is no medically acceptable alternative to the therapy provided/ tested, provided the consent has been obtained from parents / guardian;
h. Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child participant as any available alternative interventions;
i. The risk presented by interventions not intended to benefit the individual child participant is low when compared to the importance of the knowledge that is to be gained.

iii. *Vulnerable groups* : Effort may be made to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed.

a. Research on genetics should not lead to **racial inequalities**;
b. Persons who are **economically or socially disadvantaged** should not be used to benefit those who are better off than them;
c. Rights and welfare of **mentally challenged and mentally differently able persons** who are incapable of giving informed consent or those with behavioral disorders must be protected. Appropriate proxy consent from the legal guardian should be taken after the person is well informed about the

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study, need for participation, risks and benefits involved and the privacy and confidentiality procedures. The entire consent process should be properly documented;

d. Adequate justification is required for the involvement of participants such as prisoners, students, subordinates, employees, service personnel etc. Who have **reduced autonomy** as research participants, since the consent provided may be under duress or various other compelling reasons.

5. CONFIDENTIALITY FOR RESEARCH PARTICIPANTS

Safeguarding confidentiality - The investigator must safeguard the confidentiality of research data, which might lead to the identification of the individual participants.

Data of individual participants can be disclosed under the following circumstances :

a. Only in a court of law under the orders of the presiding judge or
b. There is threat to a person's life or
c. In cases of severe adverse reaction may be required to communicate to drug registration authority or
d. If there is risk to public health it takes precedence over personal right to privacy and may have to be communicated to health authority.

Therefore, the limitations in maintaining the confidentiality of data should be anticipated and assessed and communicated to appropriate individuals or authorities as the case may be.

6. COMPENSATION FOR ACCIDENTAL INJURY

Research participants who suffer physical injury as a result of their participation are entitled to financial or other assistance to compensate them equitably for any temporary or permanent impairment or disability.

In case of death, their dependents are entitled to material compensation.

Obligation of the sponsor to pay :- The sponsor whether a pharmaceutical company, a government, or an institution, should agree, before the research begins, in the *a priori* agreement to provide compensation for any physical or psychological injury for which participants are entitled or agree to provide insurance coverage for an unforeseen injury whenever possible.

An Arbitration committee or appellate authority could be set up by the institution to decide on the issue of compensation on a case-by-case basis for larger trials where such a step is feasible. Alternately an institution can also establish such a committee to oversee such claims, which would be common for projects being undertaken by it.

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Compensation for ancillary carefor unrelated illness as free treatment or appropriate referrals may also be included in the *a priori* agreement with the sponsors whenever possible.

7. MONITORING AND REPORTING ADVERSE REACTIONS OR EVENTS

Any adverse event or adverse drug reaction (AE/ ADR) can be expected and unexpected. These should be specified in the concerned SOP. Based on medical criteria they can be mild, moderate or severe/ serious and causality relationship should be examined. An AE or unexpected ADR requires expedited review by the ethics committee. Unexpected AE/ ADRs and all SAE (serious adverse event) should be reported to the sponsor by the investigator within 24 hours and to the ethics committee that accorded approval to the study protocol within seven days. In the event of death the EC should also be informed within 24 hours. Any unexpected SAE as defined in the Indian GCP (Good Clinical Practice) Guidelines occurring during a clinical trial should be communicated promptly within 14 calendar days by the Sponsor to the Licensing Authority and to the Investigator(s) of other trial sites participating in the study. The reporting of the SAE to the regulatory authority immediately is to enable it to stop the clinical trials of unapproved drugs or withdraw from market approved drugs based on report of Phase IV studies. All other serious unexpected reactions (ADRs) that are not fatal or life threatening must be filed as soon as possible but not later than 14 calendar days. At the end of the trial, all adverse events whether related to trial or not are to be listed, evaluated and discussed in detail in the final report.

The medical management of the adverse event is the responsibility of the investigator, and the protocol for adverse event management with allocation of responsibilities must be pre-defined in the protocol and submitted to the Ethics Committee. There must be a financial plan (including, if necessary, insurance) to manage adverse events and compensation for trial related injury. The Ethics Committee reviewing the protocol must review these aspects as well before giving approval.

8. CLINICAL TRIALS WITH SURGICAL PROCEDURES / MEDICAL DEVICES

Medical and health care technology has undergone rapid transformation in the past two decades. Of late, a series of technological inventions have revolutionized the preventive, diagnostic, rehabilitative, therapeutic (life-supporting or life sustaining devices) capabilities of medical sciences and biomedical technology has made considerable progress in the conceptualisation and designing of bio-equipments.

Several biomedical devices and critical care equipment have been imported and successfully deployed in diagnostic and therapeutic services in the country. Similarly, various academic and research organizations as well as private

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entrepreneurs are taking active interest in the development and manufacture of medical devices. Several important devices such as cardiac valve and spin offs from defence research laboratories like Kalam-Raju Stent, cardiac catheters, eye lasers and external cardiac pacemaker have been successfully developed and many more are in various stages of development.

However, only through good manufacturing practices (GMP) can the end products reach the stage of large scale utilisation by society. Most of these products are only evaluated by Central Excise testing for taxation purposes, which discourages entrepreneurs to venture in this area with quality products especially when they do not come under the strict purview of the existing regulatory bodies like ISI, BSI and Drugs Controller General. This is evidenced by the very low number of patents or propriety medical equipments manufactured and produced in the country.

9. DIAGNOSTIC AGENTS - USE OF RADIO - ACTIVE MATERIALS AND XRAYS

In human beings, for investigation and treatment, different radiations - X-ray, gamma rays and beta rays -, radiopaque contrast agents and radioactive materials are used. The relative risks and benefits of research proposal utilising radioactive materials or X-rays should be evaluated. Radiation limits for the use of such materials and X-rays should be in accordance with the limits set forth by the regulatory authority for such materials (BARC – Bhabha Atomic Research Centre, Mumbai).

Special Concerns

a. Informed consent should be obtained before any diagnostic procedures.
b. Information to be gained should be gathered using methods that do not expose participants to more radiation than exposed normally.
c. In the event of death of a participant with radiological implant, due precaution as'per radiation guidelines may be taken not to expose the relatives or the close co-habitants to radiation till safe.
d. Research should be performed on patients undergoing the procedures for diagnostic or therapeutic purposes.
e. Safety measures should be taken to protect research participants and others who may be exposed to radiation.
f. The protocol should make adequate provisions for detecting pregnancies to avoid risks of exposure to the embryo.
g. Information must be given to participant about possible genetic damage to offspring.
h. Non-radioactive diagnostic agents are considered as drugs and the same guidelines should be followed when using them.
i. Ultrasound should be substituted wherever feasible.

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10. CLINICAL EVALUATION OF TRADITIONAL *AYURVEDA, SIDDHA, UNANI* (ASU) REMEDIES AND MEDICINAL PLANTS

Self medication and greater orientation towards preventive health care, the growing desire of the aging population to stay young and healthy, and the increasing healthcare costs of therapy provided by Modern Medicine have led to more usage of traditional remedies. However, the improved research technology tools and growth deciders like new Biotechnology developments for producing the evidence, together with media publicity have catapulted traditional knowledge to the status of a hidden treasure worth exploring. Nevertheless, subjecting traditional remedies to the same rigours that synthetic drugs undergo to establish their safety and efficacy is a difficult proposition, as most of them are complex combinations leading to difficulty in assessment of their activity and risk/benefit ratio. This involves four sets of issues - chemical-manufacturing-control (CMC) issues, non-clinical issues, clinical issues, and ethical issues.

11. EPIDEMIOLOGICAL STUDIES

Epidemiological studies are generally considered in two categories – observational and experimental. Designs of these studies are based on cross-sectional, case-control or cohort approaches. Epidemiological studies cover research, programme evaluation and surveillance. Ethics in epidemiological studies is multidimensional covering clinical medicine, public health and the social milieu. The code of ethics is much better understood for clinical research, where the interaction between a patient and a clinical researcher is of supreme importance. In epidemiological research the researcher is dealing with a group of individuals and the questions faced by an epidemiologist are more of a professional nature. These questions would pertain to interactions with individual participants, sources of funding or employer, fellow epidemiologist and the society at large. Need for a code of ethics for epidemiologists is being recognized globally and the issues for such a code in the context of epidemiological research in India deserve attention.

Epidemiological research differs from clinical research in the context of the large number of study participants and generally a long time frame. If some mistakes or aberrations get detected during the course of conduct of such studies, repeating the whole exercise will be expensive, time consuming and may not even be feasible.

Hence utmost care needs to be taken for various aspects - technical, practical and ethical.

DEFINITIONS

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Observational Epidemiology : In observational studies predefined parameters in a defined population group over a specified period and frequency are recorded for studying exposure to risks affecting health. These may be of the following types :

a. Cross Sectional Studies (Surveys) : This is primarily population based and involves selecting an entire population or random samples of the representative population based on census data and then using questionnaires to understand the prevalence of various diseases. Its aim is to assess aspects of the health of a population or to test hypotheses about possible cause of disease or suspected risk factors. The study participants are directly contacted only once in the defined period for which informed consent is required to be taken.

b. Case Control Studies: This usually compares the past history of exposure to risks among patients who have a specified condition/disease (cases) with the past history of exposure to this among persons who resemble the cases in such respects as age, sex socioeconomic status, geographic location, but who do not have the disease (controls). Case control studies can be done by following up available records, usually records in a hospital, but in the context of a country like ours it may require direct contact between research workers and study participants and informed consent to participate in the study is necessary. However, if it entails only a review of medical records, informed consent may not be required and indeed may very often not be feasible. But for such waiver of consent approval from IEC would be necessary.

c. Cohort Studies: These are longitudinal or prospective studies of a group of individuals with differing exposure levels to suspected risk factors. They are observed over a long period usually several years. The rate of occurrence of the condition of interest is measured and compared in relation to identified risk factors. It requires a study of large number of participants for a long time and involves asking questions, checking of records, routine medical examination and sometimes laboratory investigations. Individuals are being followed up as the cohort and it is essential to identify precisely every individual to be studied.

Experimental Epidemiology : In experimental epidemiology the investigators alter one or more parameters under controlled conditions to study the effects of the intervention on health. These are usually randomised controlled trials done to test a preventive or therapeutic regimen or the efficacy of a diagnostic procedure. Although these are strictly speaking epidemiological studies they come under the purview of clinical evaluation of drugs /devices / products / vaccines etc. The possibility of use of placebo as one of the arm of the trial should be explained and informed consent taken in such studies.

SPECIFIC PRINCIPLES

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1. **Informed Consent** : When individuals are to be included as participants of any epidemiological studies, the purpose and general objectives of the study has to be explained to them keeping in mind their level of understanding. It needs to be ensured that privacy will be maintained. In the context of developing countries, obtaining informed consent has been considered many times as difficult/ impractical / not meeting the purpose on various grounds such as incompetence to comprehend the meaning or relevance of the consent and culturally being dependent on the decision of the head of the family or village/ community head. However, **there is no alternative to obtaining individual's informed consent** but what should be the content of the informed consent is also a crucial issue. In spite of obtaining informed individual consent, it is quite likely that the participants/ patients may not be fully aware of their rights. In this context, the role of investigator is crucial and s/he should remain vigilant and conscious of her/ his obligations towards the participants/ patients, all through the course of the studies.
2. In most epidemiological research it would be necessary to have the **consent of the community,** which can be done through the Village Leaders, the Panchayat head, the tribal leaders *etc.* who are considered to be gate keepers of the society/ community
3. In obtaining the consent of individuals or communities it is important to keep in mind that working through peer groups or through Panchayat etc. may mean that the individuals or community would feel reluctant to disagree and refuse to give consent because of **societal pressures**. This is something that has **to be carefully avoided**.
4. Particularly in a country like India, with the level of poverty that is prevalent it is easy to use inducements, especially financial inducements, to get individuals and communities to consent. **Such inducements are not permissible**. However, it is necessary to provide for adequate compensation for loss of wages and travel / other expenses incurred for participating in the study.
5. **All risks involved** including the risk of loss of privacy must be explained to the participants in an epidemiological study. Steps should be taken to maintain utmost privacy which should be informed to the community.
6. **Maintaining confidentiality** of epidemiological data is absolutely essential. A particular concern is the fact that some population based data may also have implications on issues like national security and these need to be carefully evaluated at the beginning.
7. All attempts should be made to **minimise harm** to the individuals and society at large. Special consideration for the cultural characteristics of

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the communities that are being studied is essential to prevent any disturbance to cultural sensitivities because of the investigation.

8. The design of the study should ensure that the **benefits of the study are maximised** for the individuals and communities taking part in the study. This means that at the onset itself the investigators should design the way in which the results of the study are going to be communicated and also decide whether individuals identified at particular risk during the course of the studies would be informed. It may also be necessary in some instances to inform the concerned family members about the results, for instance, as in AIDS, STD etc. It may not always be possible to communicate study results to individuals but research findings and advice should be publicized by appropriate available means. It is also important that the beneficial results of epidemiological studies are fed into the health system and necessary training modules should be developed as part of the epidemiological project.
9. In all situations where there is likely to be **conflicts of interest** it must be ensured that the interest of the individuals involved in the study are protected at all cost, for *eg.,* studies on outbreaks, epidemics, disasters and calamities, and epidemiological studies undertaken by providers of relief and rehabilitation.
10. Scientific objectivity should be maintained with honesty and impartiality, both in the design and conduct of the study and in presenting and interpreting findings. Selective withholding of data and similar practices are unethical.
11. Benefits : When epidemiological studies (like those on mortality and morbidity as a result of exposure to an agent) lead to long associations with the community, the results if released in timely manner could give improved health care facilities or educate the community to reduce the impact of adverse environment on health and tackle the problem at their end in time.
12. Ethical Review Procedures: In all Ethical Committees at least one or two individuals with an understanding of the principles of epidemiological ethics have to be included. These Committees should be independent and comprise of epidemiologists, clinicians, statisticians, social scientists, philosophers, legal experts and representatives from community/ voluntary groups who should be aware of local, social and cultural norms, as this is the most important social control mechanism.
13. Distinction between research and programme evaluation: It is difficult to make a distinction between epidemiological research and programme evaluation.

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Whenever a programme evaluation and surveillance is launched, the monitoring and evaluating mechanisms should clearly be planned and cleared by IEC before initiation as is done in all epidemiological studies.

It is not always possible to know what will happen to the participants as unexpected results or undesirable events can sometimes occur. Very often the benefits and risks of the research pertain not only to the individual participants, but also the community from which they are drawn. Therefore, the participation of local community representatives in planning, conducting and monitoring research is important to avert circumstances which may be detrimental to the participants' welfare. This also helps in improving the vision of the researcher regarding the objectives and the design of study. The inclusion of a community representative to act on behalf of all participants involved in a research study Communities should be informed of the research, possible outcomes (positive and negative), and the results of the research. Research findings belong to participants and their communities as well as the researchers and the research community. Community representatives and researchers can work together to make sure that research is conducted in the most appropriate way and the benefits if any, could be shared in a reasonable or workable manner.

42. APPLICATION PROCEDUREFOR ETHICAL CLEARANCE

All Principal Investigators are requested to submit new project proposals for the review of Ethics Committee to The Institutional Ethical Committee (IEC), room no 2, Block- A, Surendera Dental College & Research Institute in the prescribed format along with documents according to the list of documents.

1. A cover letter (**Annexure 1**),
2. Principal Investigator form - Form I (**Annexure 2**)
3. Review form – From II (**Annexure 3**). Fill only the sections required to be filled by Principal Investigator
4. Decision Letter – Form III (**Annexure 4**). Fill only the sections required to be filled by Principal Investigator
5. Research Protocol :
   a. Introduction: Should clearly identify the need for the present research (why it is important to conduct this research). Safety of proposed intervention and any drug or vaccine to be tested, including results of relevant laboratory, animal and human research
   b. Aims and Objectives:
   c. Materials and methods:

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1. Participant recruitment procedures

2. Procedure for seeking and obtaining informed consent

3. Inclusion and exclusion criteria for entry of participants.

4. Precise description of methodology of the proposed research, including
   sample size (with justification), type of study design (observational, **experimental, pilot, randomized, blinded**etc.), intended intervention,
   dosages of drugs, route of administration, duration of treatment and details of invasive procedures if any.

5. In case the research involves a study product (such as a pharmaceutical or device under investigation, an adequate summary of all safety, pharmacological pharmaceutical and toxicological data available on the study product, together with a summary of clinical experience with the study product to date (e.g.: recent investigator's brochure published data, a summary of the product's characteristics); (Product information)
6. Plan to withdraw or withhold standard therapies in the course of research.
7. For research involving more than minimal risk, an account of management of such risk or injury
8. Proposed compensation and reimbursement of incidental expenses, if planned
9. A statement of maintaining privacy and confidentiality of the study participants
10. A statement of agreement to comply with national and international Good Clinical Practices (GCP) protocols for clinical trials
11. Details of Funding agency/ Sponsors and fund allocation, if any
12. A statement on conflict-of-interest (COI), if any
13. Plan for statistical analysis of the study.

d. References: Appropriate references
e. Annexures (if any): example - Case report forms, questionnaires, handouts intended for research participants
f. Informed consent form in local language and English (**Annexure 5**)
g. For international collaborative study details about foreign collaborators and documents for review of Health Ministry's Screening Committee(HMSC) or appropriate Committees under other agencies/ authority like Drug Controller General of India (DCGI)

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h. For exchange of biological material in international collaborative study a MoU/ Material Transfer Agreement between the collaborating partners.
i. All previous IEC 's decisions(e.g., those leading to a negative decision or modified protocol) by other ECS or regulatory authorities for the proposed study(whether in the same location or elsewhere) and an indication of modification(s) to the protocol made on that account. The reasons for previous negative decisions must be provided.
j. Summary of research protocol in non-technical language.

6. Consent form (Annexure 5). The researcher may choose the appropriate consent form from the forms provided in the annexure 5.
7. **Fees**: A non-refundable fees of INR 200 will be taken along with the submission of the study protocol.

The decision on the study protocol will be intimated through e-mail after review by the reviewer and conduct of next EC meeting.

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Annexure 1: Covering Letter

Application for Ethical Review of Biomedical Research Proposal

To

The Chairman

Institutional Ethical Committee

Surendera Dental College and Research Institute

HH Gardens

Karni Road

Sri Ganganagar

Rajasthan- 335001

Date:

Full name of applicant :_____

Designation:

Complete Postal Address:

Mob No:

e-mail:

Title of Project:

Sir,

I am submitting my research protocol for approval by the Ethical Committee. I have submitted the required list of documents in the prescribed format along with my application.

Thanking you,

Yours Sincerely

Signature (Principal Investigator)

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Annexure – II (Principal investigator form)

Form to be filled by the Principal Investigator (PI) for submission to Institutional Ethics Committee (IEC)

(for attachment to each copy of the proposal as per ICMR guidelines)

Serial No of IEC :

(To be filled by IEC office)

Proposal Title:

	Name, Designation & Qualifications	Address Tel & Fax Nos. Email ID	Signature
PI			
Co-PI / Collaborators 1.			
2.			
3.			

Tick appropriately

Sponsor Information :

1. Indian	a) Government	☐	Central	☐	State	☐	Institutional ☐
	b) Private	☐					
2. International	Government	☐	Private	☐	UN agencies	☐	
3. Industry	National	☐	Multinational	☐			

Contact Address of Sponsor (if applicable):

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Total Budget (if applicable/sponsored) :

1.Type of Study : Epidemiological ☐ Basic Sciences ☐ Animal studies ☐

Clinical: Single center ☐ Multicentric ☐ Behavioral ☐

2. Status of Review: New ☐ Revised ☐

3. Clinical Trials:
Drug /Vaccines/Device/Herbal Remedies :

i. Does the study involve use of :
Drug ☐ Devices ☐ Vaccines ☐

Indian Systems of Medicine/ Alternate System of Medicine ☐ Any other ☐ NA ☐

ii. Is it approved and marketed
In India ☐ UK & Europe ☐ USA ☐

Other countries, specify ☐

iii. Does it involvea change in use, dosage, route of administration?	Yes	No
If yes, whether DCGI's /Any other Regulatory authority's Permission is obtained?	Yes	No
If yes, Date of permission :		
iv. Is it an Investigational New Drug?	Yes	No
If yes, IND No:		
a). Investigator's Brochure submitted	Yes	No
b). *In vitro* studies data	Yes	No
c). Preclinical Studies done	Yes	No
d). Clinical Study is : Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐		
e). Are you aware if this study/similar study is being done elswhere ?	Yes	No
If Yes, attach details		

4. Description of the proposal – Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale :

ATTACHED SYNOPSIS COPY

5. Privacy and confidentiality

i. Study involves - Direct Identifiers ☐
Indirect Identifiers/coded ☐
Completely anonymised/ delinked ☐

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i. Confidential handling of data by staff	Yes	No
6. Use of biological/ hazardous materials i. Use of fetal tissue or abortus	Yes	No
ii. Use of organs or body fluids	Yes	No
iii. Use of recombinant/gene therapy	Yes	No
If yes, has Department of Biotechnology (DBT) approval for rDNA products been obtained?	Yes	No
iii. Use of pre-existing/stored/left over samples	Yes	No
v. Collection for banking/future research	Yes	No
vi. Use of ionising radiation/radioisotopes	Yes	No
If yes, has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes	No
vii. Use of Infectious/biohazardous specimens	Yes	No
viii. Proper disposal of material	Yes	No
ix. Will any sample collected from the patients be sent abroad ? **If Yes, justify with details of collaborators**	Yes	No
a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration? b) Sample will be sent abroad because (Tick appropriate box): Facility not available in India ☐ Facility in India inaccessible ☐ Facility available but not being accessed. ☐ If so, reasons…	Yes	No

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7. Consent : *Written ☐ Oral ☐ Audio-visual ☐

i. Consent form : (tick the included elements)

Understandable language	☐	Alternatives to participation	☐
Statement that study involves research	☐	Confidentiality of records	☐
Sponsor of study	☐	Contact information	☐
Purpose and procedures	☐	Statement that consent is voluntary	☐
Risks & Discomforts	☐	Right to withdraw	☐
Benefits	☐	Consent for future use of biological material	☐
Compensation for participation	☐	Benefits if any on future commercialization eg. genetic basis for drug development	☐
Compensation for study related injury	☐		

*If written consent is not obtained, give reasons:

ii. Who will obtain consent ? PI/Co-PI ☐ Nurse/Counsellor ☐ Research staff ☐ Any other ☐

8. Will any advertising be done for recruitment of Subjects ? (posters, flyers, brochure, websites – if so kindly attach a copy)	Yes	No
9. Risks & Benefits: i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country?	Yes	No
ii. Is there physical / social / psychological risk / discomfort? **If Yes,** Minimal or no risk ☐ More than minimum risk ☐ High risk ☐	Yes	No
Iii.Is there a benefit a) to the subject ? Direct ☐ Indirect ☐ b) Benefit to society ☐		
10. Data Monitoring i. Is there a data & safety monitoring committee/ Board (DSMB)?	Yes	No
ii. Is there a plan for reporting of adverse events ? **If Yes,** reporting is done to : Sponsor ☐ hics Committee D☐IB ☐	Yes	No
iii. Is there a plan for interim analysis of data?	Yes	No
vi. Are there plans for storage and maintenance of all trial database? **If Yes,** for how long ?	Yes	No
11. Is there compensation for participation? **If Yes,** Monetary ☐ In kind ☐ Specify amount and type:	Yes	No
12. Is there compensation for injury? **If Yes,** by Sponsor ☐ by Investigator ☐ by insurance company ☐ by any other ☐	Yes	No

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13. Do you have conflict of interest? (financial/nonfinancial) If Yes, specify :	Yes	No

Checklistforattacheddocuments:

Project proposal – 2 Copies (1hard/1soft on CD)	☐
Patient information sheet	☐
Informed Consent form	☐
Investigator's brochure for recruiting subjects	☐
Copy of advertisements/Information brochures	☐
Copy of clinical trial protocol and/or questionnaire	☐
Institutional Animal Ethics Committee clearance	☐
CPCSEA clearance, if any	☐
HMSC/DCGI/DBT/BARC clearance if obtained	☐

Place:

Signature & Designation of PI/Co-PI/Collaborator

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Annexure-III (Reviewer's form)

Institutional Ethics Committee Review Form

Serial No of IEC (to be filled by IECOffice):

----------To be filled by Investigators----------

Proposal Title:

Principal Investigator: **Co-investigator:** 1.
2.
3.

Supporting Agency: ICMR/ non ICMR

If non ICMR, name of agency:

----------To be filled by reviewer----------

Project Status: New ☐ Revised ☐

Review: Regular ☐ Interim ☐

Date of Review:

1. Research Design

i.	Scientifically sound enough to expose subjects to risk	Yes ☐	No ☐
ii.	Relevant to contribute to further knowledge	Yes ☐	No ☐
iii	Of national importance	Yes ☐	No ☐

2 Risks

a. Is there physical/social/psychological risk/discomfort?	Yes ☐	No ☐
c. Is the overall risk/benefit ratio	Acceptable ☐	Unacceptable ☐

3 Benefits

Direct: Reasonable ☐ Undue ☐ None ☐

Indirect: Improvement in science/knowledge ☐ Any other ☐

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4 Subject selection :

i Inclusion / exclusion criteria addressed? Yes ☐ No ☐

ii Vulnerable subjects (woman, child, mentally challenged, seriously or terminally ill, foetus, economically or socially backward and healthy volunteers) adequately protected ? Yes ☐ No ☐

iii. Special group subjects (captives, students, nurses & dependant staff) adequately protected? Yes ☐ No ☐

Privacy & Confidentiality maintained? Yes ☐ No ☐

Patient Information Sheet: Adequate ☐ Inadequate ☐

7. Consent form components addressed adequately? Yes ☐ No ☐

8. Compensation, (if applicable) addressed adequately? Yes ☐ No ☐

9. Is there a Conflict of Interest? Yes ☐ No ☐

If yes, Acceptable ☐ Unacceptable ☐

10. Budget: Appropriate ☐ Inappropriate ☐

11. Decision of review

Recommended ☐ Recommended with suggestions ☐

Revision ☐ Rejected ☐

Any other remarks/suggestions:

Reviewers names and Signatures

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Annexure-IV (Decision form)

Communication of Decision of the Institutional Ethics Committee (IEC)

(Fields 1,2 and 3 to be filled by investigators)

IEC No:

1.Protocol title
2.Principal Investigator:
3.Name & Address of Institution:
☐ New review ☐ Revised review ☐ Expedited review
Date of review (D/M/Y): Date of previous review, if revised application:
Decision of the IEC/ IRB: ☐ Recommended ☐ Recommended with suggestions ☐ Revision ☐ Rejected
Suggestions/ Reasons/ Remarks:
Recommended for a period of :

Please note *

- **Inform IEC immediately in case of any Adverse events and Serious adverse events.**
- **Inform IEC in case of any change of study procedure, site and investigator**
- **This permission is only for period mentioned above. Annual report to be submitted to IEC.**
- **Members of IEC have right to monitor the trial with prior intimation.**

Principal
SDCRI

Chairman
IEC

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Member Secretary
IEC

Annexure – V (various consent forms)

Informed Consent Form Template for Clinical trials

(This template is for either clinical trials or clinical research)
(language used throughout form should be at the level of a local student of class 6th/8th)

Notes to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study. **The logo of the Institution must be used on the ICF and not the WHO logo.**

2. The informed consent form consists of two parts: the information sheet and the consent certificate.

3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.

4. This template includes examples of key questions that may be asked at the end of each section, that could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions, and the investigators will have to modify the questions depending upon their study.

5. In this template:
   - square brackets indicate where specific information is to be inserted
   - bold lettering indicates sections or wording which should be included
   - standard lettering is used for explanations to researchers only and must not be included in your consent forms. The explanation is provided in black, and examples are provided in red in italics. Suggested questions to elucidate understanding are given in black in italics.

TEMPLATE ON FOLLOWING PAGE

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[Name of Principle Investigator]

[Informed Consent form for _____ _____]

Name the group of individuals for whom this informed consent form is written.Because research for a single project is often carried out with a number of different groups of individuals - for example healthcare workers, patients, and parents of patients - it is important that you identify which group this particular consent is for.

(Example: This Informed Consent Form is for men and women who attend clinic Z, and who we are inviting to participate in research on X. The title of our research project is "……")

You may provide the following information either as a running paragraph or under headings as shown below.

[Name of Principal Investigator]
[Name of Organization]
[Name of Sponsor]
[Name of Proposal and version]

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

Briefly state who you are and explain that you are inviting them to participate in the research you are doing. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the participant that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions now or later.

(Example: I am X, working for the Y Research Institute. We are doing research on Z disease, which is very common in this country. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.)

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Purpose of the research

Explain in lay terms why you are doing the research. The language used should clarify rather than confuse. Use local and simplified terms for a disease, e.g. local name of disease instead of malaria, mosquito instead of anopheles, "mosquitoes help in spreading the disease" rather than "mosquitoes are the vectors". Avoid using terms like pathogenesis, indicators, determinants, equitable etc.There are guides on the internet to help you find substitutes for words which are overly scientific or are professional jargon.

(Example: Malaria is one of the most common and dangerous diseases in this region. The drugs that are currently used to help people with malaria are not as good as we would like them to be. In fact, only 40 out of every 100 people given the malaria drug XYZ are completely cured. There is a new drug which may work better. The reason we are doing this research is to find out if the new drug ABX is better than drug XYZ which is currently being used.)

Type of Research Intervention

Briefly state the type of intervention that will be undertaken. This will be expanded upon in the procedures section but it may be helpful and less confusing to the participant if they know from the very beginning whether, for example, the research involves a vaccine, an interview, a biopsy or a series of finger pricks.

(Example: This research will involve a single injection in your arm as well as four follow-up visits to the clinic.)

Participant selection

State why this participant has been chosen for this research. People often wonder why they have been chosen to participate and may be fearful, confused or concerned.

(Example: We are inviting all adults with malaria who attend clinic Z to participate in the research on the new malaria drug.)

- ***Example of question to elucidate understanding:*** *Do you know why we are asking you to take part in this study? Do you know what the study is about?*

Voluntary Participation

Indicate clearly that they can choose to participate or not. State, what the alternative - in terms of the treatment offered by the clinic - will be, if they decide not to participate. State, only if it is applicable, that they will still receive all the services they usually do whether they choose to participate or not. This can be repeated and expanded upon later in the form as well, but it is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context.

(Example: Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will offered the treatment that is routinely offered in this clinic/hospital for disease Z, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.)

- ***Examples of question to elucidate understanding:*** *If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?*

Include the following section only if the protocol is for a clinical trial:

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Information on the Trial Drug [Name of Drug]

1) give the phase of the trial and explain what that means. Explain to the participant why you are comparing or testing the drugs.
2) provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.
3) explain the known experience with this drug
4) explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial

(Example: The drug we are testing in this research is called ABX. It has been tested before with people who do not have malaria but who live in areas where malaria is common. We now want to test the drug on people who have malaria. This second research is called a "phase 2" trial.

The drug ABX is made by Company C. You should know that it has a few side effects. One of the side effects, or problems, is that you may feel tired for the first day after being given the drug. Also, 20% of the people who tried the drug in previous research experienced temporary swelling where the injection entered the skin. We know of no other problem or risks.

Some participants in the research will not be given the drug which we are testing. Instead, they will be given the drug XYZ, the drug which is most commonly used in this region to treat malaria. There is no risk associated with that drug and no known problems. It does not, however, cure malaria as often as we would like.)

Procedures and Protocol

Describe or explain the exact procedures that will be followed on a step-by-step basis, the tests that will be done, and any drugs that will be given. Explain from the outset what some of the more unfamiliar procedures involve (placebo, randomization, biopsy, etc.) Indicate which procedure is routine and which is experimental or research.Participants should know what to expect and what is expected of them. Use active, rather than conditional, language. Write "we will ask you to…." instead of "we would like to ask you to….".

In this template, this section has been divided into two: firstly, an explanation of unfamiliar procedures and, secondly, a description of process.

A. Unfamiliar Procedures

This section should be included if there may be procedures which are not familiar to the participant.

If the protocol is for a clinical trial:

1) involving randomization or blinding, the participants should be told what that means and what chance they have of getting which drug (i.e. one in four chances of getting the test drug).

(Example:. Because we do not know if the new malaria drug is better than the currently available drug for treating malaria, we need to compare the two. To do this, we will put people taking part in this research into two groups. The groups are selected by chance, as if by tossing a coin.

Participants in one group will be given the test drug while participants in the other group will be given the drug that is currently being used for malaria. It is important that neither you nor we know which of the two drugs you are given. This information will be in our files, but we will not look at these files until after the research is finished. This is the best way we have for testing without being influenced by what we think or hope might happen. We will then compare which of the two has the best results.

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The healthcare workers will be looking after you and the other participants very carefully during the study. If we are concerned about what the drug is doing , we will find out which drug you are getting and make changes. If there is anything you are concerned about or that is bothering you about the research please talk to me or one of the other researchers)

2) involving an inactive drug or placebo, it is important to ensure that the participants understand what is meant by a placebo or inactive drug.

(Example: A placebo or inactive medicine looks like real medicine but it is not. It is a dummy or pretend medicine. It has no effect on a person because it has no real medicine in it. Sometimes when we want to know whether a new medicine is good, we give some people the new medicine and some people the pretend or dummy medicine. For the research to be good, it is important that you do not know whether you have been given the real medicine or the pretend or dummy medicine. This is one of the best ways we have for knowing what the medicine we are testing really does.)

3) which may necessitate a rescue medicine, then provide information about the rescue medicine or treatment such as what it is and the criterion for its use. For example, in pain trials, if the test drug does not control pain, then intravenous morphine may be used as a rescue medicine.

(Example:. If we find that the medicine that is being used does not have the desired effect, or not to the extent that we wish it to have, we will use what is called a "rescue medicine." The medicine that we will use is called QRS and it has been proven to control pain. If you find that the drug we are testing does not stop your pain and it is very uncomfortable for you, we can use the rescue medicine to make you more comfortable.)

<u>If the protocol is for clinical research:</u>
Firstly, explain that there are standards/guidelines that will be followed for the treatment of their condition. Secondly, if as part of the research a biopsy will be taken, then explain whether it will be under local anesthesia, sedation or general anesthesia, and what sort of symptoms and side effects the participant should expect under each category.

(Example: You will receive the treatment of your condition according to national guidelines. This means that you will be (explain the treatment). To confirm the cause of your swelling, a small sample of your skin will be taken. The guidelines say that the sample must be taken using a local anesthesia which means that we will give you an injection close to the area where we will take the sample from. This will make the area numb so that you will not feel any pain when we take the sample.)

<u>For any clinical study (if relevant):</u>
If blood samples are to be taken explain how many times and how much in a language that the person understands. It may, for example, be inappropriate to tell a tribal villager that blood equal to a wine-glass full will be taken but it may be very appropriate to use pictures or other props to illustrate the procedure if it is unfamiliar.

If the samples are to be used only for this research, then explicitly mention here that the biological samples obtained during this research procedure will be used only for this research, and will be destroyed after ____ years, when the research is completed. If the tissues/blood samples or any other human biological material will be stored for a duration longer than the research purpose, or is likely to be used for a purpose other than mentioned in the research proposal, then provide information about this and obtain consent specifically for such storage and use in addition to consent for participation in the study - (see last section)

(Example: We will take blood from your arm using a syringe and needle. Each time we will take about this much blood (show a spoon, vial or other small container with a small amount of water in it.

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In total, we will take about .....this much blood in x number of weeks/months. At the end of the research, in 1 year, any left over blood sample will be destroyed.)

B. Description of the Process

Describe to the participant what will happen on a step-by-step basis. It may be helpful to the participant if you use drawings or props to better illustrate the procedures. A small vial or container with a little water in it is one way of showing how much blood will be withdrawn.

(Example: During the research you make five visits to the clinic.

- *In the first visit, a small amount of blood, equal to about a teaspoon, will be taken from your arm with a syringe. This blood will be tested for the presence of substances that help your body to fight infections. We will also ask you a few questions about your general health and measure how tall you are and how much you weigh.*
- *At the next visit, which will be two weeks later, you will again be asked some questions about your health and then you will be given either the test drug or the drug that is currently used for malaria. As explained before, neither you nor we will know whether you have received the test or the dummy/pretend drug.*
- *After one week, you will come back to the clinic for a blood test. This will involve....)*

Duration

Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.

(Example: The research takes place over ___ (number of) days/ or ___ (number of) months in total. During that time, it will be necessary for you to come to the clinic/hospital/health facility _____(number of) days , for ____ (number of) hours each day. We would like to meet with you three months after your last clinic visit for a final check-up.

In total, you will be asked to come 5 times to the clinic in 6 months. At the end of six months, the research will be finished.)

- ***Examples of question to elucidate understanding:****Can you tell me if you remember the number of times that we are asking you to come to the hospital to complete the treatment? The research project? How many injections will you be given? How many tablets? How much blood will be taken from your veins, using a syringe and needle? Over how many weeks? Etc. Do you have any other questions? Do you want me to go through the procedures again?*

Side Effects

Potential participants should be told if there are any known or anticipated side effects and what will happen in the event of a side effect or an unexpected event.

(Example: As already mentioned, this drug can have some unwanted effects. It can make you tired and it can cause some temporary swelling around the place where the injection goes into your arm. It is possible that it may also cause some problems that we are not aware of. However, we will follow you closely and keep track of any unwanted effects or any problems. We may use some other medicines to decrease the symptoms of the side effects or reactions. Or we may stop the use of one or more drugs. If this is necessary we will discuss it together with you and you will always be consulted before we move to the next step.)

Risks

Explain and describe any possible or anticipated risks.Describe the level of care that will be available in the event that harm does occur, who will provide it, and who will pay for it. A risk can be thought

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of as being the possibility that harm may occur. Provide enough information about the risks that the participant can make an informed decision.

(Example: By participating in this research it is possible that you will be at greater risk than you would otherwise be. There is, for example, a risk that your disease will not get better and that the new medicine doesn't work even as well as the old one. If, however, the medicine is not working and your fever does not go down in 48 hours we will give you quinine injections which will bring your fever down and make you more comfortable.

While the possibility of this happening is very low, you should still be aware of the possibility. We will try to decrease the chances of this event occurring, but if something unexpected happens, we will provide you with_____.)

- ***Examples of question to elucidate understanding:*** *Do you understand that, while the research study is on-going, no-one may know which medicine you re receiving? Do you know that the medicine that we are testing is a new medicine, and we do not know everything about it? Do you understand that you may have some unwanted side-effects from the medicines? Do you understand that these side-effects can happen whether or not you are in the research study? Etc. Do you have any other questions?*

Benefits

Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation. Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question.

(Example: If you participate in this research, you will have the following benefits: any interim illnesses will be treated at no charge to you. If your child falls sick during this period he/she will be treated free of charge. There may not be any benefit for you but your participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.)

Reimbursements

State clearly what you will provide the participants with as a result of their participation. WHO does not encourage incentives. However, it recommends that reimbursements for expenses incurred as a result of participation in the research be provided. These may include, for example, travel costs and money for wages lost due to visits to health facilities. The amount should be determined within the host country context.

(Example:. We will give you [amount of money] to pay for your travel to the clinic/parking and we will give you [amount] for lost work time. You will not be given any other money or gifts to take part in this research.)

- ***Examples of question to elucidate understanding:*** *Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be re-imbursed? Do you have any other questions?*

Confidentiality

Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant which would otherwise be known only to the physician but would now be available to the entire research team.Note thatbecause something out of the ordinary is being

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done through research, any individual taking part in the research is likely to be more easily identified by members of the community and is therefore more likely to be stigmatized.

(Example: With this research, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given toanyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc].)

- ***Example of question to elucidate understanding:****Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you have any questions about them?*

Sharing the Results
Where it is relevant, your plan for sharing the information with the participants should be provided. If you have a plan and a timeline for the sharing of information, include the details. You should also inform the participant that the research findings will be shared more broadly, for example, through publications and conferences.

(Example: The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. After these meetings, we will publish the results in order that other interested people may learn from our research.)

Right to Refuse or Withdraw
This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section to ensure that it fits for the group for whom you are seeking consent. The example used here is for a patient at a clinic.

(Example: You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this clinic in any way. You will still have all the benefits that you would otherwise have at this clinic. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this clinic will not be affected in any way.)
OR
(Example: You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.)

Alternatives to Participating
Include this section only if the study involves administration of investigational drugs or use of new therapeutic procedures. It is important to explain and describe the established standard treatment.

(Example: If you do not wish to take part in the research, you will be provided with the established standard treatment available at the centre/institute/hospital. People who have malaria are given....)

Who to Contact

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Provide the name and contact information of someone who is involved, informed and accessible (a local person who can actually be contacted. State also that the proposal has been approved and how.

(Example: If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e-mail])

This proposal has been reviewed and approved by [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, telephone number.]). It has also been reviewed by the Ethics Review Committee of the World Health Organization (WHO), which is funding/sponsoring/supporting the study.

- ***Example of question to elucidate understanding:*** *Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.*

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Certificate of Consent

This section should be written in the first person and have a statement similar to the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. The certificate of consent should avoid statements that have "I understand...." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant _____

Date _____
Day/month/year

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ **AND** **Thumb print of participant**

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Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.
2.
3.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year

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Informed Parental Consent Form Template for Children

(This template is for either clinical trials or clinical research)
(language used throughout form should be at the level of a local student of class 6th/8th)

Notes to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study.

2. The informed consent form consists of two parts: the information sheet and the consent certificate.

3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.

4. This template includes examples of key questions that may be asked at the end of each section, that could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions, and the investigators will have to modify the questions depending upon their study.

5. In this template:
   - square brackets indicate where specific information is to be inserted
   - bold lettering indicates sections or wording which should be included
   - standard lettering is used for explanations to researchers only and must not be included in your consent forms. The explanation is provided in black, and examples are provided in red in italics. Suggested questions to elucidate understanding are given in black in italics.

TEMPLATE ON FOLLOWING PAGE

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Surendra Dental College & Research Institute, Sri Ganganagar

[Name of Principal Investigator]

[Informed Consent Form for _____]

Name the group of individuals for whom this consent is written. Because research for a single project is often carried out with a number of different groups of individuals - for example healthcare workers, patients, and parents of patients - it is important that you identify which group this particular consent is for.

(This informed consent form is for the parents of children between the ages of 1 and 4 years of age who attend clinic Z, and who we are asking to participate in research X)

[Name of Principal Investigator]
[Name of Organization]
[Name of Sponsor]
[Name of Proposal and version]

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you agree that your child may participate)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet
Introduction

Briefly state who you are. and explain that you are inviting them to have their child participate in research which you are doing. Inform them that may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want their child to participate or not. Assure the parent that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions now or later.

(I am X, working for the Y Research Institute. We are doing research on Z disease, which is very common in this country.

I am going to give you information and invite you to have your child participate in this research. You do not have to decide today whether or not you agree that your child may participate in the research. Before you decide, you can talk to anyone you feel comfortable with.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.)

Purpose

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Explain the problem/research question in lay terms which will clarify rather than confuse. Use local and simplified terms for a disease, e.g. local name of disease instead of malaria, mosquito instead of anopheles, "mosquitoes help in spreading the disease" rather than "mosquitoes are the vectors". Avoid using terms like pathogenesis, indicators, determinants, equitable etc.There are guides on the internet to help you find substitutes for words which are overly scientific or are professional jargon.

Recognize that parents' feelings about involving their children in research can be complicated. The desire and feeling of responsibility to protect their child from risk or discomfort may exist alongside the hope that the study drug will help either their child or others. It is, therefore, important to provide clear and understandable explanations, and to give parents time to reflect on whether they will consent to have their child participate.

(Malaria is one of the most common and dangerous diseases in this region. The vaccine that is currently being used is not as good as we would like it to be but there is a new vaccine which may work better. The purpose of this research to test the new vaccine to see if it protects young children better than the current vaccine).

Type of Research Intervention
Briefly state the intervention if you have not already done so. This will be expanded upon in the procedures section.

(An injection OR a series of three injections OR taking a vaccine orally, a biopsy).

Participant selection
State clearly why you have chosen their child to participate in this study.Parents may wonder why their child has been chosen for a study and may be fearful, confused or concerned. Include a brief statement on why children, rather than adults, are being studied.

(The vaccine has been found to be effective with adults and older children. Because of how young children grow and develop, we can't assume that the vaccine will be as effective on young children unless we test it on children

We are inviting you to take part in this research because it is important that we test a new vaccine on children who do not have malaria but who live in an area where malaria is a serious problem. Because you and your child live in this area and your child does not have malaria, we are asking if you would allow your child to participate.)

- ***Example of question to elucidate understanding:*** *Do you know why your child has been identified as a potential research participant? Do you know what the study is about?*

Voluntary Participation
Indicate clearly that they can choose to have their child participate or not. State, if it is applicable, that they will still receive all the services they usually do if they decide not to participate.This can be repeated and expanded upon later in the form as well. It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context.

(Your decision to have your child participate in this study is entirely voluntary. It is your choice whether to have your child participate or not. If you choose not to consent, all the services you and your child receive at this clinic will continue and nothing will change. You may also choose to change your mind later and stop participating, even if you agreed earlier, and the services you and/or your child receives at the clinic will continue.)

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- ***Examples of question to elucidate understanding:*** *If you decide that you do not want your child to take part in this research study, do you know what your options for him/her are? Do you know that you do not have to accept that your child takes part in this research study? Do you have any questions?*

Include the following section only if the protocol is for a clinical trial:

Information on the Trial Drug [Name of Drug]

1) give the phase of the trial and explain what that means. Explain to the parent why you are comparing or testing the drugs.
2) provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.
3) explain the known experience with this drug
4) explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial

(The ABX vaccine has been tested twice before but only with older children and adults. In both studies, the vaccine worked better than the vaccine that currently exist. While the current vaccine protects only 60% of people who take the vaccine the new one protected more than 80% of the people The new vaccine also protected for a longer time period. We want to compare those two vaccines - the current one and the new one - in a younger age group, and that is why we are doing this research.

The drug is made by Company AB, who is working with a local hospital to have it tested. Its called a _____type of drug because it helps part of the blood to_____. The new vaccine that we are studying has no known side effects. The current vaccine that is being used in the study also has no known side effects.)

Procedures and Protocol

It is important that the parents know what to expect and what is expected of them and their child. Describe or explain the exact procedures that will be followed on a step-by-step basis, the tests that will be done, and the drugs that will be given. It is also important to explain from the outset what some of the more unfamiliar procedures involve (placebo, randomization, biopsy, etc.) Describe very clearly which procedure is routine and which is experimental or research. Explain that the parent may stay with the child during the procedures. If the researchers are to have access to the child's medical records, this should be stated.

Use active, rather than conditional, language. Write "we will ask you to…." instead of "we would like to ask you to….".

In this template, this section has been divided into two: firstly, an explanation of unfamiliar procedures and, secondly, a description of process.

A. Unfamiliar Procedures

If the protocol is for a clinical trial:

1) involving randomization or blinding, the participants should be told what that means and what chance they have of getting which drug (i.e. one in four chances of getting the test drug). A very minimal statement is provided below to give you an example. You may need to be more explicit about what is exactly involved.

(Because we do not know if the new vaccine is better than the currently available vaccine for treating this disease, we need to make comparisons. Children taking part in this research will be put into groups which are selected by chance, as if by tossing a coin.

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One group will get the vaccine we are testing, and the other group will get the malaria vaccine which is currently used in this region. It is important that neither you nor we know which of the two vaccines your child was given. This information will be in our files, but we will not look at these files until after the research is finished. This is the best way we have for testing vaccines without being influenced by what we think or hope might happen. We will then compare which of the two has the best results.

The healthcare workers will be looking after you and the other participants very carefully during the study. If we are concerned about what the medicines or treatment is doing , we will find out which vaccine your child is getting and make changes.)

2) involving a placebo it is important to ensure that the participants understand what is meant by a placebo. An example for a placebo is given below.

(A placebo or inactive medicine looks like real medicine but it is not. It is a dummy or pretend medicine. It has no effect on a person because it has no real medicine in it. Sometimes when we want to know whether a new medicine is good, we give some people the new medicine and some people the pretend or dummy medicine. For the research to be good, it is important that you and your child do not know whether the real medicine or the pretend or dummy medicine was given. This is one of the best ways we have for knowing what the medicine we are testing really does.)

3) which may necessitate a rescue medicine, then provide information about the rescue medicine or treatment such as what it is and the criterion for its use. For example, in pain trials, if the test drug does not control pain, then intravenous morphine may be used as a rescue medicine

(If we find that the medicine that is being used does not have the desired effect, or not to the extent that we wish it to have, we will use what is called a "rescue medicine.".)

B. Description of the Process

Describe the process on a step-by-step basis.

(You may stay with your child during each of the visits and during the procedures. In the first visit, a small amount of blood, equal to about a teaspoon will be taken from your child's arm. This will be tested for the presence of substances that help your child's body to fight infections. Your child will feel some discomfort when the needle stick goes into her/his arm but this will go away very quickly. There may be slight bruising but this will disappear in a few days.

In the next visit, your child will be given either the test vaccine or the vaccine that is currently being used for malaria in this region. Neither you nor we will know, until later in the study, which vaccine your child was given. The vaccine will be given by a trained healthcare worker. After the vaccine, we ask that you and your child stay at the clinic for 30 minutes so that the healthcare worker can observe any immediate changes in the child's mood, and if swelling occurs around the injection site. We will give you and your child juice and something small to eat.

We will ask your child's physician to give us the details of your child's health and illness related information. If you do not wish us to do that, please let us know. However ,because your child's health records are very important for the study, if we cannot look at the health records, we will not be able to include your child in the study.

At the end of the study, we will contact you by letter to tell you which of the two vaccines your child was given....)

In case of a clinical research:

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Explain that there are standards/guidelines that must be followed. If a biopsy will be taken, then explain whether it will be under local anesthesia, sedation or general anesthesia, and what sort of symptoms and side effects the participant should expect under each category.

(Your child will receive the treatment for his/her condition according to national guidelines, etc. The sample will be taken using a local anesthesia which means that only the part of your child that we are taking the sample from, and a small surrounding area, will lose feeling for a short time. Your child shouldn't feel pain, etc.)

For any clinical study (if relevant):
If blood samples are to be taken explain how many times and how much in a language that the person understands. It may, for example, be inappropriate to tell a tribal villager that blood equal to a table-spoon full will be taken.

If the tissues/blood samples or any other human biological material will be stored for a duration longer than the research purpose, or is likely to be used for a purpose other than mentioned in the research proposal, then provide information about this and obtain consent specifically for such storage and use in addition to consent for participation in the study - (see last section)

If not, then explicitly mention here that the biological samples obtained during this research procedure will be used only for this research, and will be destroyed after ___ years, when the research is completed.

Duration
Include a statement about the time commitments of the research for the participant and for the parent including both the duration of the research and follow-up, if relevant.

(The research takes place over ___ (number of) days/ or ___ (number of) months in total. During that time, it will be necessary for you to come to the clinic/hospital/health facility _____(number of) days, for ____ (number of) hours each day. We would like to meet with you six months after your last visit for a final check-up. Altogether, we will see you and your child 4 times over a year).

- ***Examples of question to elucidate understanding:****Can you tell me if you remember the number of times that we are asking you to come to the hospital to complete the treatment? The research project? How many injections will you be given? How many tablets? How much blood will be taken from your veins, using a syringe and needle? Over how many weeks? Etc. Do you have any other questions? Do you want me to go through the procedures again?*

Side Effects
Parents should be told if there are any known or anticipated side effects and what will happen in the event of a side effect or an unexpected event.

(These vaccines can have some unwanted effects or some effects that we are not currently aware of. However, we will follow your child closely and keep track of these unwanted effects or any problems. We will give you a telephone number to call if you notice anything out of the ordinary, or if you have concerns or questions. You can also bring your child to this health facility at anytime and ask to see [name of nurse, doctor, researcher].

We may use some other medicines to decrease the symptoms of the side effects or reactions. Or we may stop the use of one or more drugs. If this is necessary we will discuss it together with you and you will always be consulted before we move to the next step.)

Risks

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A risk can be thought of as being the possibility that harm may occur. Explain and describe any such possible or anticipated risks.Provide enough information about the risks that the parent can make an informed decision. Describe the level of care that will be available in the event that harm does occur, who will provide it, and who will pay for it.

(By participating in this research it is possible that your child will be at greater risk than he/she would otherwise be. There is a possibility that _____may happen as a result of taking this drug. While the possibility of this happening is very low, you should still be aware of the possibility. If something unexpected happens and harm does occur, we will provide your child with_____. [explain the level of care that will be available, who will provide it, and who will pay for it. Inform the parent if there is a particular insurance in place.])

Discomforts

Explain and describe the type and source of any anticipated discomforts that are in addition to the side effects and risks discussed above.

(By participating in this research it is possible that your child may experience some discomfort such as the discomfort of the injections. There may be a slight hardening and/or swelling where the needle stick goes into the skin. This should disappear in one day. Your child may also be fussier than usual or more tired. These behaviors usually stop within one day but if you are concerned, please call me or come to the clinic.)

- ***Examples of question to elucidate understanding:*** *Do you understand that, while the research study is on-going, no-one may know which medicine your child is receiving? Do you know that the medicine that we are testing is a new medicine, and we do not know everything about it? Do you understand that your child may have some unwanted side-effects from the medicines? Do you understand that these side-effects can happen whether or not your child is in the research study? Etc. Do you have any questions?*

Benefits

Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question. Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation.

(If your child participates in this research, he/she will have the following benefits: any interim illnesses will be treated at no charge to you. If your child falls sick during this period he/she will be treated free of charge. There may not be any other benefit for your child but his/her participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.)

Reimbursements

State clearly what you will provide the participants with as a result of their participation. WHO does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in research. The expenses may include, for example, travel expenses and reimbursement for time lost. The amount should be determined within the host country context.

(You will not be provided any incentive to take part in this research. However, you will be reimbursed with - provide a figure if money is involved - for your lost time and travel expense.)

- ***Examples of question to elucidate understanding:*** *Can you tell me if you have understood correctly the benefits that your child will have if you allow him/her to take part in the study?*

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Do you know if the study will pay for your and your child's travel costs and your time lost, and do you know how much you will be re-imbursed? Do you have any other questions?

Confidentiality

Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant, which would otherwise be known only to the physician but would now be available to the entire research team. Because something out of the ordinary is being done through research, any individual taking part in the research is likely to be more easily identified by members of the community and is therefore more likely to be stigmatized.

(The information that we collect from this research project will be kept confidential. Information about your child that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about your child will have a number on it instead of his/her name. Only the researchers will know what his/her number is and we will lock that information up with a lock and key. It will not be shared with or given toanyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc].)

- ***Example of question to elucidate understanding:****Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you and/or your child will remain confidential? Do you have any questions about them?*

Sharing of the results

Your plan for sharing the information with the participants and their parents should be provided. If you have a plan and a timeline for the sharing of information, include the details. Also inform the parent that the research findings will be shared more broadly, for example, through publications and conferences.

(The knowledge that we get from this study will be shared with you before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. Afterwards, we will publish the results in order that other interested people may learn from our research).

Right to Refuse or Withdraw

This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section well to ensure that it fits for the group for whom you are seeking consent. The example used here is for a parent of an infant at a clinic.

(You do not have to agree to your child taking part in this research if you do not wish to do so and refusing to allow your child to participate will not affect your treatment or your child's treatment at this Centre in any way. You and your child will still have all the benefits that you would otherwise have at this Centre. You may stop your child from participating in the research at any time that you wish without either you or your child losing any of your rights as a patient here. Neither your treatment nor your child's treatment at this Centre will be affected in any way.)

Alternatives to participating

Include this section only if the study involves administration of investigational drugs or use of new therapeutic procedures. It is important to explain and describe the established standard treatment.

(If you do not wish your child to take part in the research, your child will be provided with the established standard treatment available at the centre/institute/hospital. People who have malaria are given....)

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Who to Contact

Provide the name and contact information of someone who is involved, informed and accessible (a local person who can actually be contacted.) State also that the proposal has been approved and how.

(If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e-mail]
This proposal has been reviewed and approved by [name of the IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, telephone number.])

PART II: Certificate of Consent

Certificate of Consent
This section should be written in the first person and have a statement similar to the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. The certificate of consent should avoid statements that have "I understand...." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

(I have been invited to have my child participate in research of .....). **I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily for my child to participate as a participant in this study.**

Print Name of Participant_____

Print Name of Parent or Guardian_____

Signature of Parent or Guardian _____

Date _____
Day/month/year

If illiterate
A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.
I have witnessed the accurate reading of the consent form to the parent of the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

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Print name of witness_____ **AND** **Thumb print of parent**

Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the parent of the potential participant, and to the best of my ability made sure that the person understands that the following will be done:

1.
2.
3.

I confirm that the parent was given an opportunity to ask questions about the study, and all the questions asked by the parent have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year

An Informed Assent Form will_____ OR will not _____ be completed.

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Informed Consent Form Template for

Consent for Storage and Future Use of Samples

Notes to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study.

2. The informed consent form consists of two parts: the information sheet and the consent certificate.

3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.

4. In this template:
   - square brackets indicate where specific information is to be inserted
   - bold lettering indicates sections or wording which should be included
   - standard lettering is used for explanations to researchers only and must not be included in your consent forms. The explanation is provided in black, and examples are provided in red in italics. Suggested questions to elucidate understanding are given in black in italics.

TEMPLATE ON FOLLOWING PAGE

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Surendera Dental College & Research Institute

Additional Consent to [Name of Project]

Include the following section if the research protocol calls for storage and future use of samples

This Statement of Consent consists of two parts:

- **Information Sheet (to share information about unused samples with you)**
- **Certificate of Consent (to record your agreement)**

You will be given a copy of the full Statement of Consent

Part 1. Information Sheet

Explain that you are seeking permission to store their unused samples for possible future use in either your own research or someone else's research. State that they need to make some decisions about their blood/tissue/sperm/sputum sample because they gave you permission only to use it for the current research.

Explain that sometimes people don't want their samples used for research into areas they might not agree with, for example, research into birth control or reproductive technology. Use lay terms to explain research possibilities. If genetic research is a possibility, explain what this is and any implications for them. State that they can tell you if there is something they don't want their sample used for, or if they don't want their sample used at all.

Inform the participant that at present, the researchers can trace which blood/tissue/sperm/sputum sample belongs to the participant. In most cases, the participant must decide whether they want to let the researchers keep the sample but get rid of all identifying information, or whether they are comfortable with the researchers knowing whose sample it is. Explain the risks and benefits of each of these options. Inform the participant of researcher obligations in cases where the sample remains linked. These obligations include informing the participant of results which have immediate clinical relevance.

Inform participants that their sample will not be sold for profit and that any research which uses their sample will have been approved.

Right to Refuse and Withdraw

Explain that the participant may refuse to allow samples to be kept or put restrictions on those samples with no loss of benefits and that the current research study will not be affected in any way. Inform the participant that they may withdraw permission at anytime and provide them with the name, address, and number of the person and sponsoring institution to contact.

Confidentiality

Briefly explain how confidentiality will be maintained including any limitations.

You can ask me any more questions about any part of the information provided above, if you wish to. Do you have any questions?

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Part II. Certificate of Consent

If any of the (TYPE OF SAMPLE i.e. blood, tissue) I have provided for this research project is unused or leftover when the project is completed (Tick **one** choice from each of the following boxes)

- ☐ I wish my [TYPE OF SAMPLE] sample to be destroyed immediately.
- ☐ I want my [TYPE OF SAMPLE] sample to be destroyed after ____ years.
- ☐ I give permission for my [TYPE OF SAMPLE] sample to be stored indefinitely

AND (if the sample is to be stored)

- ☐ I give permission for my (TYPE OF SAMPLE) sample to be stored and used in future research but only on the same subject as the current research project : [give name of current research]
- ☐ I give my permission for my [TYPE OF SAMPLE] sample to be stored and used in future research of any type which has been properly approved
- ☐ I give permission for my [TYPE OF SAMPLE] sample to be stored and used in future research except for research about [NAME TYPE OF RESEARCH]

AND

- ☐ I want my identity to be removed from my (TYPE OF SAMPLE) sample.
- ☐ I want my identity to be kept with my (TYPE OF SAMPLE) sample.

I have read the information, or it has been read to me. I have had the opportunity to ask questions about it and my questions have been answered to my satisfaction. I consent voluntarily to have my samples stored in the manner and for the purpose indicated above.

Print Name of Participant_____

Signature of Participant _____

Date _____
Day/month/year

If illiterate
A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ **AND** **Thumb print of participant**

Signature of witness _____

Date _____

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Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.
2.
3.

I confirm that the participant was given an opportunity to ask questions about the nature and manner of storage of the samples, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year

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